

EXHIBIT 3

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VIDEOTAPED DEPOSITION BY VIDEOCONFERENCE
OF
GOURANG P. PATEL, B.S. CHEM, PHARM.D., MSc.,
FCCM, BCPS, BCCCP

February 11, 2022

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION
CAUSE NO. 3:18-CV-01234

TERRY LYNN KING,)
)
Plaintiff,)
)
-vs-)
)
TONY PARKER, et al.,)
)
Defendants.)
- - - - -)

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S T I P U L A T I O N

The deposition of DR. GOURANG P. PATEL, called as a witness at the instance of the Plaintiff, taken pursuant to all rules applicable to the Federal Rules of Civil Procedure, by agreement, on the 11th of February 2022, at each participant's respective location due to the COVID-19 pandemic, Tennessee, before Brenda L. Davis, LCR, RPR, RMR, pursuant to stipulation of counsel.

It being agreed that Brenda L. Davis, LCR, RPR, RMR may report the deposition in machine shorthand, afterwards reducing the same to typewriting.

All objections except as to the form of the question are reserved to on or before the hearing.

It being further agreed that all formalities as to notice, caption, certificate, transmission, etcetera, including the reading of the completed deposition by the witness and the signature of the witness, are expressly waived.

1 VIDEOGRAPHER: Good morning. We are
2 going on the record at 9:03 a.m. on
3 February 11, 2022. This is video unit number
4 one of the video-recorded deposition of
5 Dr. Gourang Patel, in the matter of Terry Lynn
6 King versus Tony Parker, et al., filed in the
7 United States District Court, Middle District
8 of Tennessee, Nashville Division, Case Number
9 3:18-CV-01234. This deposition is being held
10 remotely via Zoom.

11 Will counsel please identify themselves
12 for the record.

13 MS. NELSON-MAJOR: Good morning. My
14 name is Hayden Nelson-Major, I'm with the
15 Federal Community Defender Office for the
16 Eastern District of Pennsylvania. I represent
17 the Plaintiff in this matter, Terry King. And
18 also present with me in my office is my
19 colleague, Anna Baldrige. On the Zoom from
20 the Federal Community Defender Office is Lynne
21 Leonard and Alex Kursman and Jules Welsh.
22 Jules Welsh is a legal fellow with our office
23 and does not represent Mr. King. Also present
24 for Plaintiff's counsel is Jeremy Gunn with
25 Bass, Berry & Sims.

1 MR. SUTHERLAND: Good morning, my name
2 is Scott Sutherland, I'm a deputy attorney
3 general with the Tennessee Attorney General's
4 Office, on behalf of the Defendants Tony
5 Parker and Tony Mays. With me from our office
6 are colleagues Rob Mitchell, Dean Atiya, and
7 that's it.

8 VIDEOGRAPHER: Will the court reporter
9 please swear in the doctor.

10 DR. GOURANG P. PATEL
11 having first been duly sworn, was examined and
12 testified as follows:

13 DIRECT EXAMINATION

14 BY MS. NELSON-MAJOR:

15 Q. Good morning, Dr. Patel. Can you hear me
16 okay?

17 A. I can, yes.

18 Q. As I just mentioned, my name's Hayden
19 Nelson-Major, and I represent the Plaintiff, Terry
20 King, in this matter. You have been retained by
21 the attorneys who represent the Defendants to offer
22 an opinion in this case; is that right?

23 A. That's correct, yes.

24 Q. And you understand that you're here today
25 to answer some questions about opinions that you

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1 offered in this matter; is that right?

2 A. Affirmative.

3 Q. I appreciate you taking the time to talk
4 to us today. Do you understand what this case is
5 generally about?

6 A. I do, yes.

7 Q. And what's your understanding of what this
8 case is about?

9 A. My understanding is, it's about the
10 utilization of lethal injection chemicals for the
11 purpose of execution.

12 Q. And I understand that you've served as an
13 expert witness before, but I just want to cover a
14 couple of ground rules before we get started. You
15 understand that you're under oath today.

16 A. I do, yes.

17 Q. And do you understand that means that you
18 need to tell the truth to the best of your ability?

19 A. I do, yes.

20 Q. Have you taken any medications today that
21 might affect your ability to recall facts or give
22 accurate testimony today?

23 A. Negative.

24 Q. Have you consumed any drugs or alcohol in
25 the past 24 hours?

1 A. Negative.

2 Q. And is there any reason that you believe
3 you cannot testify truthfully or accurately today?

4 A. No, not that I'm aware.

5 Q. Are you represented by counsel today?

6 A. I believe that's correct, yes.

7 Q. And are you referring to Mr. Sutherland?

8 A. That's correct.

9 Q. And even though this deposition is being
10 taken over Zoom, the court reporter is making a
11 record based on what you say. So that means that
12 you'll need to verbally respond to the questions,
13 rather than gesturing. Do you understand that?

14 A. I do, yes.

15 Q. And so for the same reasons, I'll ask that
16 you wait for me to finish my question before you
17 start to answer. And I'll in turn try to do the
18 same, I'll let you finish your answer before I
19 answer -- before I ask the next question.

20 If you need to take a break at any time,
21 just let me know. But if there's a question
22 pending, I'll ask that you answer the question
23 before we take that break. From time to time
24 Mr. Sutherland might object to a question that I ask
25 you. But unless that objection is on the basis of a

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1 privilege, you still need to answer my question. Do
2 you understand that?

3 A. I do, yes.

4 Q. Do you have any questions about those
5 ground rules before we get started?

6 A. No.

7 Q. What did you do today to prepare -- excuse
8 me, what did you do to prepare for your deposition
9 today?

10 A. I reviewed a number of materials that
11 would have been provided in the beginning and as the
12 case has progressed, in addition to deposition
13 transcripts, a number of reports that I've already
14 cited in my report and some that I was provided --
15 that I obtained after my report was submitted.

16 Q. And what were the documents that you
17 obtained after your deposition -- excuse me, after
18 your report was submitted?

19 A. The documents that I reviewed after would
20 have been inclusive of, I believe, at least a half
21 dozen or so reports, if that. I believe they were
22 from Dr. Van Norman, there was a Dr. Williams,
23 Dr. Antognini. And, also, there was a supplemental,
24 I think report, by Dr. Almgren which was submitted.
25 And then there were some exhibits associated with

1 that.

2 Q. When did you review these documents that
3 you just listed?

4 A. It would have been shortly after probably
5 the supplemental or rebuttal report that I received.
6 So it would have been whatever that date was.

7 Q. Do you know when you received these
8 additional documents that aren't listed in your
9 report?

10 A. It probably would have been sometime
11 mid-January.

12 Q. And you mentioned that you reviewed a
13 report from Dr. Antognini. Did you review one
14 report from Dr. Antognini or multiple reports?

15 A. No, it was just one report.

16 Q. And other than the reports you just
17 listed, did you review additional documents for the
18 first time after you submitted your report in this
19 case?

20 A. Other than those materials that I listed
21 inclusive of -- there was quite a bit of materials
22 reviewed prior. But, no, I don't recall outside of
23 that.

24 Q. Did you review any depositions from the
25 experts that you just listed?

1 A. Depositions? No, I haven't seen one.

2 Q. To prepare for the deposition today, did
3 you meet with anyone from the Attorney General's
4 Office?

5 A. No, I did not physically meet with anyone
6 from the office.

7 Q. Did you have a Zoom or telephone meeting?

8 A. Yes, we had, I think, two or three phone
9 conferences over the last 30, 45 days or so.

10 Q. And who from the Attorney General's Office
11 was on those telephone calls?

12 A. It would be Mr. Atiya, Mr. Mitchell or
13 Mr. Sutherland or a mix of their team.

14 Q. And when was the last meeting that you
15 had?

16 A. We had one yesterday afternoon.

17 Q. And how long was that meeting?

18 A. Approximately 45 minutes, 50 minutes.

19 Q. And the other one to two meetings that you
20 had, how long were those, approximately?

21 A. I'd say about the same amount of time.

22 Q. Did you review any documents during those
23 meetings?

24 A. Documents? No.

25 Q. Besides the attorneys from the Attorney

1 General's Office, was anyone else present for those
2 meetings?

3 A. Not that I'm aware of, no.

4 Q. You mentioned that you reviewed some
5 expert reports to prepare for today. Did you also
6 review other materials?

7 A. It would have been anything inclusive of,
8 probably since the case started, which is on a
9 ShareFile link.

10 Q. I'm sorry, repeat that again. I didn't
11 catch that last part.

12 A. Sure. It would be any materials inclusive
13 on the ShareFile link. It includes a number of
14 documents from the State, it looks like quality
15 control, quality assurance reports from the pharmacy
16 that compounded the LICs, etcetera.

17 Q. And when you say a ShareFile link, is that
18 like a Dropbox or a Box.com site?

19 A. Probably it's more secure. I believe it's
20 through the State.

21 Q. And when you say that you reviewed quality
22 assurance reports from the pharmacies that compounds
23 drugs for TDOC, can you describe to me what those
24 documents were?

25 A. Sure. They were inclusive of analysis for

1 testing, analysis and testing of the API, the final
2 product, substituents, excipients, diluents used
3 during the compounding of the LIC, and then any
4 testing that was submitted upon the final product.

5 Q. Did those documents include a master log
6 formula for any of the drugs that are compounded for
7 TDOC?

8 A. I believe there is a couple of them that
9 are compounded. Only two out of the three are
10 actually compounded.

11 Q. And the documentation that you just
12 cataloged, did it include the master log formulas
13 for those two drugs that are compounded for TDOC?

14 A. That is my understanding, it was a
15 formula sheet. I don't recall if it was called,
16 "master log," but it was a formula sheet.

17 Q. Did that documentation also include logs
18 that the pharmacy generated when compounding
19 particular preparations for TDOC?

20 A. You'll have to define logs. I recall a
21 formula sheet and a number of papers that were on
22 that for analysis and testing before and after
23 production, but that's all I remember.

24 Q. When a pharmacy compounds a preparation,
25 do they document the steps they take to do that

1 compounding process?

2 A. Well, not necessarily. Because if you're
3 familiar with sterile compounding, you have to be
4 gowned and gloved up. So you can't actually
5 document while you're doing the process, it's done
6 after.

7 Q. After the compounding process is done, do
8 compounding pharmacies generally document the steps
9 that were performed?

10 A. That's correct. It can either be done on
11 paper, electronically, or a sign-off. It just
12 depends on the process the pharmacy has set up.

13 Q. Did you see paper or electronic forms that
14 document the compounding process that the pharmacy
15 did when preparing drugs for TDOC?

16 A. Not that I recall, no. Not to that
17 detail.

18 Q. And the quality assurance documents that
19 you referenced, were those provided to you prior to
20 you drafting the report that you offered in this
21 case?

22 A. That's correct.

23 Q. Did those documents also include logs from
24 fingertip sampling tests performed by the pharmacy?

25 A. You're probably referring to media fill.

1 No, I did not see media fill testing.

2 Q. I was actually referring to the fingertip
3 sampling first. Did you see records of that testing
4 performed?

5 A. No.

6 Q. Have you reviewed any invoices documenting
7 the purchases of drugs for TDOC?

8 A. If there were invoices inclusive of all
9 the other documents I mentioned, if they were
10 included in there then, yes, I would have reviewed
11 them.

12 Q. But you don't recall whether or not you
13 did, in fact, see those documents before?

14 A. Over the last three months, I'm sure they
15 were -- if they were inclusive in there, then I
16 reviewed them.

17 Q. And were the documents that you just
18 listed provided to you at one time or were they
19 provided to you over a series of times?

20 A. Which documents?

21 Q. You just listed a number of documents that
22 were provided to you on the file share site. Were
23 those documents provided to you all in one batch or
24 were they provided to you in several batches?

25 A. I believe it's just all at one time.

1 Q. And that was prior to you authoring your
2 report in this case.

3 A. That's correct.

4 Q. Have you reviewed any of the papers that
5 have been filed in this case?

6 A. You'll have to define for me, what papers?

7 Q. Any court filings.

8 A. No, I don't -- I didn't review any court
9 filings, or recall any.

10 Q. Did anyone consult with you to prepare for
11 another deposition in this case; such as, the other
12 experts retained by the Attorney General's Office?

13 A. We discussed the substance of my report
14 and my opinions, and they were likely, I'm sure,
15 used I'm other depositions.

16 Q. When you say, "we," you're referring to
17 Mr. Sutherland, Mr. Mitchell or Mr. Atyia?

18 A. That's correct, because it was a Q&A and
19 they asked me why my opinion was my opinion and I
20 told them.

21 Q. But you didn't speak with Dr. Antognini or
22 Dr. Li.

23 A. No, I haven't spoken with any of the
24 experts. I don't know them.

25 Q. Did you discuss this deposition with

1 anyone other than the attorneys from the Attorney
2 General's Office?

3 A. Negative.

4 Q. Did you do anything else to prepare for
5 your deposition today other than what we just
6 discussed?

7 A. No, ma'am.

8 Q. How much time in total do you estimate
9 that you've spent preparing for today?

10 A. Over the last two, two and a half weeks,
11 probably close to ten hours.

12 Q. Dr. Patel, do you have a copy of your
13 report in front of you?

14 A. No, I do not.

15 Q. We're going to e-mail a copy to
16 Mr. Sutherland, and I'm also going to share it up on
17 the share screen, if you can sit tight for a
18 moment.

19 All right. I'm going to share my screen
20 with you. Are you able to see my screen share now?

21 A. I am, yes.

22 Q. Is this a copy of the report you submitted
23 in this case?

24 A. That's correct.

25 Q. I'm going to mark this as Exhibit 1. I'm

1 going to turn to page three, and there's a heading:
2 Materials Reviewed and Relied Upon. Is this a
3 complete list of everything you reviewed when
4 working on this report?

5 A. It's probably not a list of everything
6 I've reviewed. It's inclusive of everything I
7 reviewed and cited throughout the report.

8 Q. And as you just mentioned, there's some
9 additional documents that you reviewed that aren't
10 listed on this page, correct?

11 A. That's correct. I mean, the entire
12 ShareFile is probably thousands of pages. I don't
13 have everything listed there, no.

14 Q. So you're estimating that you reviewed
15 several thousand pages of documents?

16 A. If you include 200, 300 pages per depo and
17 all the other materials, it probably is, yeah.

18 Q. Were the documents that you provided --
19 that you were provided include the discovery that
20 was produced in this case, if you're aware?

21 A. I don't know what it's labeled or called.
22 But if they were included on the ShareFile, I
23 reviewed them.

24 Q. Were you provided with records from
25 executions that TDOC has previously conducted?

1 A. That's correct. Yes.

2 Q. Were you provided with training logs for
3 training exercises that TDOC has conducted?

4 A. That's correct. I believe that was
5 included in there as well.

6 Q. Were you provided with autopsy reports
7 performed on individuals executed pursuant to TDOC's
8 protocol?

9 A. Autopsy reports? No. I don't remember
10 seeing any autopsy reports.

11 Q. So just so I understand, this section
12 here, you've listed materials that you've reviewed
13 and relied upon. But this is not a list of
14 everything that you've, in fact, reviewed to date.

15 A. That's correct. Because some of the
16 materials, as I just mentioned earlier, were after
17 this report.

18 Q. Do you recall reviewing any records of pH
19 testing performed on the drugs compounded for TDOC?

20 A. I don't recall exact pH testing logs, no.

21 Q. Have you reviewed any execution protocols
22 other than the one at issue in this case?

23 A. No, ma'am, I have not.

24 Q. So no protocols from other states.

25 A. Other states? No.

1 Q. Have you talked to anyone at TDOC who is
2 involved in carrying out executions?

3 A. No, ma'am.

4 Q. How about anyone at the pharmacy who
5 supplies TDOC with lethal injection drugs?

6 A. No, I have not.

7 Q. Have you talked to anyone affiliated with
8 TDOC about the potential use of drugs other than
9 midazolam, vecuronium bromide, and potassium
10 chloride for use at execution?

11 A. I have not, no.

12 Q. And have you spoken with anyone affiliated
13 with TDOC about how to obtain drugs for use at
14 executions?

15 A. No, I have not.

16 Q. I'm going to turn to page 11 of your
17 report. And that should still be up on your screen,
18 but let me know if it's not.

19 MR. SUTHERLAND: Ms. Nelson-Major, I
20 have e-mailed the report to Dr. Patel.

21 Dr. Patel, have you gotten your --

22 THE WITNESS: Let me see. Yeah,
23 because it's a little bit hard to --

24 MS. NELSON-MAJOR: If it's easier for
25 you to look at the pdf on your computer rather

1 than my share screen, that's fine by me.

2 THE WITNESS: Oh, okay. Thank you.

3 MR. SUTHERLAND: Did you receive the
4 e-mail?

5 THE WITNESS: I did, Scott. Thank you.
6 Yep.

7 MR. SUTHERLAND: Would you, please,
8 review that in its entirety and make sure
9 that -- just to acknowledge for the record
10 that what you have is the report that you
11 prepared?

12 THE WITNESS: That's correct. Yes,
13 sir.

14 BY MS. NELSON-MAJOR:

15 Q. So if you turn to page 11, there's a
16 numbered paragraph number one under the heading:
17 Opinions. Let me know when you're there.

18 A. Okay.

19 Q. I'm looking at the first sentence under
20 that heading Opinions, and you wrote, "My opinion is
21 that TDOC's procurement and utilization of
22 commercially manufactured and/or compounded LICs
23 will not result in or cause the inmate to experience
24 pain or suffering in the lethal injection execution
25 process." Did I read that accurately?

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1 A. That's correct.

2 Q. What about the fact that the drugs are
3 either commercially manufactured or compounded leads
4 you to the conclusion that the inmates will not
5 experience pain or suffering?

6 A. It has to actually do more with the
7 medications and their order and the doses that are
8 utilized.

9 Q. And what does LIC mean in this sentence,
10 for the record?

11 A. My understanding is that stands for in the
12 protocol lethal injection chemical.

13 Q. Then the next sentence says, "TDOC's
14 lethal injection manual describes the LIC being
15 utilized for lethal injection are either
16 FDA-approved commercially manufactured drugs or
17 shall be compounded preparations prepared in
18 compliance with pharmaceutical standards."

19 And in the footnote to that you cite
20 page 34 of the protocol. I'm going to pull up the
21 protocol, if you can hang tight. We'll e-mail it
22 to you as well. Are you able to see the protocol on
23 your screen now as well?

24 A. Just pulling it up. Give me one second.
25 I see it, yes.

1 Q. And if you'd like to take a minute to look
2 through it, that's fine. But does this appear to be
3 the protocol that you were provided by
4 Mr. Sutherland's office?

5 A. That appears to be the protocol, that's
6 correct.

7 Q. I'm going to mark this as Exhibit 2, and
8 I'm going to turn page 34, the page that you cited
9 in that opinion, and I'm going to direct you to the
10 paragraph at the bottom of the page.

11 MR. SUTHERLAND: I'm sending it to you
12 now, Dr. Patel.

13 THE WITNESS: Thank you. That will be
14 helpful. Thank you.

15 BY MS. NELSON-MAJOR:

16 Q. Are you able to read that paragraph? Or
17 would you prefer to wait until you have the pdf in
18 front of you?

19 A. I'll wait until I get the pdf, it'll be
20 easier. Okay.

21 Q. If I could direct your attention to the
22 full paragraph at the bottom of page 34 of the pdf,
23 which states that, "Chemicals used in lethal
24 injection executions will either be FDA-approved
25 commercially manufactured drugs; or, shall be

1 compounded preparations prepared in compliance with
2 pharmaceutical standards consistent with the United
3 States Pharmacopeia guidelines and accreditation
4 Departments, and in accordance with applicable
5 licensing regulations."

6 What is the United States Pharmacopeia?

7 A. It's a private -- my understanding and
8 experience is that it's a private organization that
9 has developed guidelines for sterile and non-sterile
10 compounding.

11 Q. And are they regarded as industry
12 standards in compounding?

13 A. They are enforced in industry and, from my
14 understanding, in hospitals or in pharmacies by the
15 FDA. That's correct.

16 Q. And is it often referred to as USP for
17 short?

18 A. That is correct.

19 Q. And what chapters of USP apply to the
20 compounded drug preparations prepared for TDOC?

21 A. Well, there's a number of them, because it
22 depends on which process you're talking about in the
23 preparation. But, overall, the main one is probably
24 USP 797.

25 Q. And what does USP 797 pertain to?

1 A. My understanding and experience is that it
2 pertains to the preparation of sterile compounds.

3 Q. And what are sterile compounds?

4 A. Sterile compounds are, again, medications
5 or drugs that are prepared by a hospital or a
6 pharmacy pursuant to patient care.

7 Q. Are all injectable preparations considered
8 sterile compounds under the USP?

9 A. Are all injectable preparations considered
10 sterile compounds. Injectable -- that's correct, in
11 the setting -- my understanding is that's
12 specifically in the setting of diagnosis, care,
13 treatment, and healing. That's true.

14 Q. And can you take a non-sterile ingredient
15 and compound it into a sterile preparation?

16 A. Correct, that is performed and can be
17 done.

18 Q. Returning to the paragraph on page 34 that
19 we just reviewed, what does "accreditation
20 Departments" mean in this paragraph?

21 A. Accreditation departments that -- at least
22 that I'm familiar with, are -- because the USP, from
23 my familiarity and experience, is -- they don't
24 enforce actually anything. So the accreditation
25 department, for example, for us in the hospital,

1 would be Joint Commission. So that -- at least
2 that's my understanding.

3 Q. And what's the Joint Commission?

4 A. It's a regulatory -- it's not actually a
5 regulatory body, it's a credentialing body for CMS.
6 It's one of -- there's a couple of them that do
7 this for institutions around the country, Joint
8 Commission is one of them.

9 Q. So is it your understanding that
10 "accreditation Departments" in this paragraph means
11 that TDOC will comply with standards set forth by
12 the Joint Commission?

13 A. No, that paragraph reads that the
14 preparation standards are consistent with USP, or
15 United States Pharmacopeia, and its guidelines and
16 accreditation department. That has nothing to --
17 stated there what TDOC does or doesn't do.

18 Q. Is it your understanding that this
19 "accreditation Departments" phrase requires the
20 compounding pharmacy to follow standards set forth
21 by the Joint Commission when preparing drugs for
22 TDOC?

23 A. That's correct. Except compounding
24 pharmacies aren't accredited by Joint Commission,
25 they're usually followed by the state board.

1 Q. Without telling me the state, if you are
2 aware, do you know where the compounding pharmacy is
3 located?

4 A. You're asking if I know where the
5 compounding pharmacy that actually prepares the
6 LICs?

7 Q. Yes. But if you do, I'm not asking you to
8 tell me the state. I'm just asking whether you know
9 where the compounding pharmacy that compounds drugs
10 for TDOC is located.

11 A. No, ma'am, I do not know.

12 Q. So you're not aware of which state board
13 would oversee the compounding that occurs on TDOC's
14 behalf.

15 A. No, ma'am, I don't know which state
16 they're prepared in.

17 Q. So you don't know which accreditation
18 department or set of licensing regulations would
19 govern the compounded preparations that are provided
20 to TDOC.

21 MR. SUTHERLAND: Objection to the form.
22 You can answer.

23 THE WITNESS: Well, which accreditation
24 department, it would fall within wherever
25 the pharmacy -- the state it's located within.

1 So, no, I don't know.

2 BY MS. NELSON-MAJOR:

3 Q. And do licensing regulations vary from
4 state to state?

5 A. That's correct.

6 Q. In rendering this opinion on page 11, did
7 you assume that the pharmacy and TDOC followed
8 applicable industry standards, including USP, when
9 preparing drugs for use in executions?

10 A. No, I assume that the pharmacy preparing
11 compounded preparations followed applicable USP
12 standards as required.

13 Q. And would your opinion change if you were
14 presented with information demonstrating that the
15 compounding pharmacy and TDOC deviated from those
16 standards?

17 A. In the setting and the scenario we're
18 discussing, no, my opinion doesn't change.

19 Q. And why wouldn't it change?

20 A. Because there is actually a number of -- a
21 number of reasons. The first and foremost has to do
22 with actually how they're intended for use. So
23 USP -- I believe it's on the first page even of the
24 document. But, however, that last paragraph down
25 there at the bottom states what USP does, what it's

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1 intended for, and the goal of USP. My understanding
2 is that it's pretty clear that it's in the setting
3 of, again, diagnosis, care, treatment, and healing.
4 This is not that setting.

5 Q. The protocol states that the drug shall be
6 prepared consistent with the USP. But it's your
7 opinion that the USP standards don't govern the
8 preparations because it's not a clinical setting?
9 Am I understanding that correctly?

10 A. It governs how the preparations are made
11 by the pharmacy and pharmacist that prepare them, it
12 does not necessarily govern how they're administered
13 or their -- who's actually administering them
14 because, correct, it is not a clinical setting in
15 accordance with the other things that have been
16 submitted.

17 For example, it does have testing of the
18 compound identity and potency for the lethal
19 injection chemical, it has testing for sterility.
20 But, for example, endotoxin testing, from what I
21 reviewed, was not present. But in my opinion, it
22 doesn't change anything about how it's being used or
23 the dose or the consequences to the person receiving
24 it, if that helps clarify.

25 Q. Oh, and I'm sorry to cut you off,

1 Dr. Patel, I thought you were finished.

2 A. No, no, that's okay.

3 Q. So, in your opinion, only certain portions
4 of the USP apply in this scenario.

5 A. It's not necessarily certain portions,
6 it's consistent with -- based on the information we
7 have, at least I have been provided and that we have
8 currently, and the testing that was performed and
9 how they're being utilized, prepared and
10 administered, I do not believe it's going to be
11 causing any additional -- or any pain or suffering
12 to the person receiving the chemical.

13 Q. You mentioned endotoxins. I'd like to use
14 that as an example. USP generally requires
15 compounded preparations to be tested for the
16 presence of endotoxins; is that right?

17 A. For non-sterile to sterile preparation,
18 endotoxin is required, that is correct.

19 Q. And the compounding pharmacy is taking
20 non-sterile ingredients to make a sterile
21 preparation for TDOC; is that correct?

22 A. That is my understanding, that's correct,
23 for two out of the three chemicals.

24 Q. But it's your opinion that, in doing so,
25 the compounding pharmacy need not perform that

1 required test for endotoxins because you don't think
2 it is relevant to this scenario; is that correct?

3 A. It's not necessarily that it need not be
4 performed. It's more consistent with, if it wasn't
5 performed, it won't have any consequences actually
6 because of what endotoxin is and what it does.

7 Q. I'm going to return to your report for a
8 moment. I'm looking at page 11 again. And I'm not
9 sure if you can see my screen or if you'd rather
10 pull it up yourself.

11 A. I'll just pull it up. Give me one second.
12 Okay.

13 Q. So the next part of your opinion, you
14 state, "Compounding pharmacies ensure that CSPs are
15 correctly prepared, sterilized, packaged, labeled,
16 sealed, stored, and dispensed."

17 Here are you making a statement about what
18 compounding pharmacies should do?

19 A. That is the responsibility of the
20 compounding pharmacy, that's correct.

21 Q. Do compounding pharmacies ever make errors
22 in preparation?

23 A. I believe any institution or pharmacy
24 that's preparing compounded sterile preparations, it
25 is not devoid of an error, that's correct.

1 Q. And the same would be true for
2 preparation, sterilization, labeling, sealing,
3 storing, and dispensing?

4 A. That's correct, an error could occur in
5 any points of that process, at any time.

6 Q. And have significant errors in compounding
7 sterile preparations led to an increased call in
8 regulation and monitoring of compounding pharmacies
9 in recent years?

10 A. That's correct. The consequences that I'm
11 familiar with are due to infection, which would
12 manifest hours to days after. But that's correct,
13 yes.

14 Q. And is that the only area in which you're
15 aware of errors occurring at compounding pharmacies?

16 A. There have been errors with concentration.
17 There have been errors with predominantly infection
18 control, as I just mentioned, which have been
19 probably the vast majority.

20 Q. I'm going to stop sharing my screen for a
21 moment. As we were discussing, throughout your
22 report you note that the protocol mandates that
23 compounded preparations be compared -- excuse me,
24 prepared in compliance with USP standards.

25 Does USP set standards for active

1 pharmaceutical ingredients?

2 A. USP has -- they're not standards, they're
3 actually monographs for active pharmaceutical
4 ingredients, that's correct.

5 Q. And what is an active pharmaceutical
6 ingredient?

7 A. It's exactly as it states, it's the active
8 ingredient that is going to go into the compounded
9 sterile preparation. The USP is just one of
10 probably four accepted ones that exist. Of course,
11 in addition to the European, British, and Japanese
12 Pharmacopeia.

13 Q. And compounding pharmacies in the United
14 States, do they generally follow the USP when
15 compounding preparations?

16 A. The com-- actual physical compounding of
17 the preparation, that's correct, within the U.S.
18 they're following the United States Pharmacopeia
19 recommendations.

20 Q. You just mentioned monographs. What are
21 the monographs?

22 A. Monographs are set up for the active
23 pharmaceutical ingredients, or I'll refer them to as
24 APIs, and those are set forth, again, by the United
25 States Pharmacopeia, which are inclusive, for

1 example, of, again, the active ingredient, the -- it
2 has to do with stability, the color, the dryness, or
3 lack thereof, and then testing, which is done on a
4 number of different -- testing for not just the
5 active chemical but a number of different impurities
6 within the API itself.

7 Q. So each monograph sets particular quality
8 requirements for a specific drug; is that right?

9 A. That's correct, that is the standard
10 across the USP, the British Pharmacopeia, the
11 European Pharmacopeia, and the Japanese
12 Pharmacopeia, from my understanding.

13 Q. And does the monograph also specify the
14 methodology that is to be used when measuring each
15 quality requirement?

16 A. That's correct, each one of those
17 pharmacopeias which is intended for compounded
18 sterile preparations for humans within that country
19 dictates and outlines what their criteria are and
20 how they will be tested.

21 Q. And how does a compounding pharmacist use
22 that monograph?

23 A. A compounding pharmacist is probably most
24 often utilizing the Certificate of Analysis that has
25 been performed on the API, and they're reviewing the

1 Certificate of Analysis that's already been
2 performed prior to beginning their compounding
3 process.

4 Q. And what's a Certificate of Analysis?

5 A. The Certificate of Analysis is actually
6 sent from the manufacturer of the API, which is
7 inclusive of all those variables I discussed
8 earlier.

9 Q. So it documents the test results
10 performed?

11 A. That's correct. It documents a number of
12 things, including identification of the compound,
13 any issues with the color or how it should actually
14 appear when it was produced and sent out, and,
15 again, any testing for impurities that was done
16 respective of which compound that they're actually
17 sending it out with.

18 Q. And what does it mean for something to be
19 USP grade?

20 A. USP grade means it has been verified
21 against the USP monograph, from my understanding.

22 Q. And so in order for API to be considered
23 USP grade, it has to meet all of the standards set
24 forth in the monograph for that particular API?

25 A. That's correct.

1 Q. And you've mentioned some of these quality
2 requirements. I just want to ask you about a couple
3 of them. What does identification mean?

4 A. Identification is identifying the active
5 pharmaceutical ingredient and, depending on the
6 compound, it outlines a percentage, which, again, is
7 pretty much universal across the four pharmacopeias.

8 Q. And what is assay?

9 A. Do you mean assay?

10 Q. I do mean that.

11 A. Oh, sorry.

12 Q. I'm new to this terminology. Please
13 excuse me.

14 A. No, I wanted to make sure it wasn't a
15 different term. The assay is basically the testing
16 that's performed on the active pharmaceutical
17 ingredient. And the assay is, again, after the type
18 of testing required. From what I recall, the
19 different amounts and testing that are done with the
20 products here at question can be either high-
21 performance liquid chromatography or liquid
22 chromatography or infrared spectrometry, or IR.

23 Q. And those three methods you just mentioned
24 are three different ways of testing the assay?

25 A. That's correct.

1 Q. Is assay the same thing as potency?

2 A. Identification -- the identifi-- I believe
3 the entire first part of that states identification
4 assay. But that's correct, it lists not necessarily
5 -- it's semi-equivalent to potency. But it's how
6 much percentage of the true active pharmaceutical
7 ingredient is in that container when it's received,
8 or shipped out.

9 Q. And those measures, taken together, tell
10 you whether what's inside the vial is of the
11 strength it's supposed to be; is that correct?

12 A. Well, for -- are you asking about the API
13 still? Or are we talking about the final prepared
14 CSP?

15 Q. I'm still asking about the API.

16 A. Oh. Then it just is the active
17 pharmaceutical ingredient. And those are -- from
18 what I understand, they could be in vials, larger
19 vials, or they're in, generally, bulk containers.

20 Q. And another quality requirement that I
21 think I heard you mention was drying. Can you
22 explain that to me as well?

23 A. Sure. It has to do with the amount of
24 humidity, as that can impact the active
25 pharmaceutical ingredient before it's used for

1 preparation. It's pretty standard with any bulk
2 chemical and generally for powders.

3 Q. And is endotoxins another quality
4 requirement that the USP generally says should be
5 tested on API?

6 A. That is in there as well. And endotoxin,
7 again, is defined as the amount of dead bacteria
8 that can generate a pyrogen response, which is -- in
9 layman terms, is a fever.

10 Q. And what about impurities, is that another
11 quality requirement?

12 A. That is, impurities are a quality
13 requirement. And as I had mentioned, it's fairly
14 standard across the four pharmacopeias, they just do
15 it a little bit differently.

16 Q. And how is it done differently across the
17 pharmacopeias?

18 A. It depends on which pharmacopeia you
19 actually go with. So, for example, European
20 Pharmacopeia, again, established in Europe for
21 treatment of -- utilizing the APIs and CSP
22 preparation for treatment of humans in Europe, has
23 the impurities -- for example, of midazolam, if we
24 look at the eight impurities on the USP monograph
25 and put it side by side by the European monograph,

1 the European monograph actually tests for one
2 additional impurity that the USP does not. So they
3 actually cover the exact same impurities, they're
4 almost verbatim. I think the USP had a total of
5 eight and, if I recall correctly, European tests for
6 nine.

7 Q. And the information about all these
8 quality measures, you stated, is provided on a
9 Certificate of Analysis for the API; is that
10 accurate?

11 A. The monograph is not on the Certificate of
12 Analysis. The Certificate of Analysis is the
13 testing that's associated with the monograph. But
14 that's correct, it's provided, from my
15 understanding, with the shipment of an API.

16 Q. And so when a compounding pharmacy
17 purchases API, the manufacturer of the API provides
18 that Certificate of Analysis to the compounding
19 pharmacy.

20 A. That is correct. That is the standard
21 operating protocol, or SOP.

22 Q. So you've mentioned some of the other
23 pharmacopeias out there, you mentioned the British
24 Pharmacopeia, the European Pharmacopeia, and the
25 Japanese Pharmacopeia. Are those the other three

1 main pharmacopeias that you're aware of?

2 A. Well, there are more. But those three in
3 addition to the U.S. pharmacopeia is the one the USP
4 most often associates with its standards. And
5 that's why I said those are the four that are fairly
6 equivalent across the board. That's correct.

7 Q. But there are differences in acceptable
8 values for the same criteria amongst the different
9 pharmacopeias. Is that also accurate?

10 A. From my understanding and review, they're
11 almost all verbatim spot on. But if there's a
12 percentage difference of 0.01 in an impurity of one
13 versus a 0.15 of another, I would say that's
14 negligible. But that would be a difference, that's
15 correct.

16 Q. But there could be a circumstance in which
17 a drug API is tested, passes the USP, but fails the
18 European Pharmacopeia based on the differences in
19 values; is that right?

20 A. My understanding is, is that for the
21 impurities, it's just actually how they're
22 performed. So, for example, the USP would test for
23 the individual impurities. The European
24 Pharmacopeia has additional testing that's already
25 picking up the other eight impurities, so they don't

1 have direct percentages associated. But that's
2 correct, it could pass on one and not on another.

3 Q. And I understand that you're saying that
4 impurity quality requirement has very little
5 differences, in your opinion, between USP and the
6 European Pharmacopeia. I'm asking a more general
7 question, which I think you answered in the
8 affirmative, is that could one drug -- the same drug
9 pass under the European Pharmacopeia but fail under
10 the USP pharmacopeia. And I think your answer was
11 yes. Am I right?

12 A. That's correct, the reverse is also true.
13 So it can pass on a European, British, or Japanese
14 Pharmacopeia and fail the USP.

15 Q. And I think you mentioned this as well.
16 But there are differences in the methodologies
17 required under the European Pharmacopeia, the USP,
18 the BP for the same test. Is that also true?

19 A. As a general statement, yes. For the
20 chemical in question, no, they're identical.

21 Q. And what's the chemical in question?

22 A. Well, the potassium chloride certificate I
23 reviewed stated USP. So the only one in question is
24 midazolam.

25 Q. And so you disagree with Dr. Almgren's

1 analysis of the differences between the USP
2 monograph, the EP monograph, and the BP monograph
3 for midazolam. Is that what you're saying?

4 A. I would respectfully disagree, that's
5 correct. If you put them up side by side and
6 actually go through the testing and the analysis,
7 the European Pharmacopeia, as I had mentioned, if
8 you do that, actually picks up an additional
9 impurity that the USP does not.

10 Q. And, in your opinion, is it irrelevant
11 that the USP, the EP, and the BP require different
12 testing methodology for assessing that value?

13 MR. SUTHERLAND: Objection to the form.

14 Did you say relevant or irrelevant?

15 MS. NELSON-MAJOR: Irrelevant.

16 MR. SUTHERLAND: Could you rephrase the
17 question, Hayden. I'm sorry.

18 BY MS. NELSON-MAJOR:

19 Q. So my question, if there are differences
20 in methodology between the three pharmacopeias, in
21 your opinion, that's irrelevant to the actual
22 conclusion that they're equivalent.

23 A. If there are true differences in the
24 methodology, my understanding is, at least reviewing
25 the only chemical in question that it would be

1 applicable to, it is irrelevant. Because if we put
2 them side by side, USP uses liquid chromatography,
3 European uses liquid chromatography, USP recommends
4 infrared, or IR, identification, European already
5 has on the first line IR. They're almost virtually
6 the same, or equivalent.

7 Q. I'm so sorry, Dr. Patel, I thought you
8 were finished.

9 A. That's okay.

10 Q. And when you're preparing compounded drugs
11 in a clinical setting, do you use the methodologies
12 set forth in the USP when you are doing these
13 quality assessments on your drugs?

14 A. The USP is what's recommended, that's
15 correct.

16 Q. And if you're compounding a USP-grade
17 preparation, are you free to pick and choose the
18 methodology for a particular quality requirement, or
19 do you have to follow the methodologies set forth in
20 USP?

21 A. If I'm compounding it, again, in the
22 setting of diagnosis, care, treatment, and healing,
23 I would be following the USP recommendations, that's
24 correct.

25 Q. Why?

1 A. That is what's required within the setting
2 of hospitals and/or stand-alone pharmacies in the
3 setting of diagnosis, treatment, healing, and
4 caring.

5 Q. In your experience, do manufacturers
6 located in the United States who make API for
7 compounding pharmacies in the United States subject
8 their API to USP standards?

9 A. My understanding is, that's correct.
10 Except if we look at the actual bigger picture, then
11 everybody's familiar with that the majority of
12 U.S. owned companies manufacturing are actually not
13 stateside, they're abroad.

14 Q. And why wouldn't such a pharmacy in the
15 example that I just gave you use EP or BP standards
16 when selling API to a compounding pharmacy in the
17 United States?

18 A. They are held to where the manufacturing
19 plant is. If it's within Europe, then it'd be the
20 European Pharmacopeia, and that's what would be
21 coming with the API. If it's coming from the UK, it
22 would have the BP Pharmacopeia. If it's coming from
23 Japan, it would have the Japan Pharmacopeia.
24 Because that's what's required, again, for the
25 treatment of -- diagnosis, treatment, care, and

1 healing for humans within that country or state.

2 Q. And that phrase that you've used several
3 times, can you -- "the treatment, care, and healing
4 of humans" -- am I accurately paraphrasing that?

5 A. That's correct. That's my understanding
6 of why the USP, pharmacopeia, was developed. It's
7 in, again, the last paragraph on the first page.

8 Q. And are you suggesting that the USP
9 standards don't govern the drugs compounded for
10 TDOC because we're not talking about the treatment,
11 care, and healing of humans?

12 MR. SUTHERLAND: Objection to the form.

13 THE WITNESS: The standards apply to
14 how the preparations are -- again, how the
15 compounded sterile preparations are prepared
16 and stored and dispensed. They do not apply
17 to TDOC, nor anybody on the TDOC premises.

18 BY MS. NELSON-MAJOR:

19 Q. The question I'm asking is, whether those
20 standards apply to the compounding pharmacy that is
21 preparing the sterile preparations for TDOC.

22 A. If that compounding pharmacy is within the
23 U.S., then yes, it would apply to them.

24 Q. I'm going to pull up one of the
25 Certificate of Analysis that you've alluded to, if

1 you could hang tight with me. I'm going to share my
2 screen again, but you also have this sent to you in
3 the e-mail. Are you seeing that on your screen now?

4 A. Let's see.

5 Q. You'll probably have to zoom out to the
6 right proportion. I'm not sure how it's showing up
7 on your screen.

8 MR. SUTHERLAND: Dr. Patel, I'm
9 forwarding you the pdf as we speak.

10 A. No problem. I got it. Okay.

11 Q. You've seen this Certificate of Analysis
12 before, right?

13 A. I believe -- yes, I have.

14 Q. I'm going to mark it as Exhibit 3. Can
15 you see that under "CERTIFICATE OF ANALYSIS" it
16 says, "MIDAZOLAM, EP"?

17 A. I do, yes.

18 Q. And then I'm going to scroll down to the
19 bottom of the page, where it states, "The above
20 mentioned product conforms to the specifications of
21 EP."

22 Does that indicate to you that this API was
23 subjected to European Pharmacopeia standards?

24 A. That's correct, that testing was performed
25 aligned with the European Pharmacopeia.

1 Q. So this Certificate of Analysis does not
2 confirm that the API meets USP standards on the face
3 of the document; is that correct?

4 A. That's correct, it is not on USP
5 monograph.

6 Q. And the fact that it's not based on USP
7 monograph means that this API cannot be considered
8 USP grade. Is that also correct?

9 A. That is correct.

10 Q. Does the fact that the API was subjected
11 to EP standards indicate that it was purchased from
12 a European source?

13 A. That means -- I don't understand the --
14 quite -- purchased from a European source. My
15 understanding is that the manufacturer is likely
16 overseas.

17 Q. Do compounding pharmacies generally
18 purchase API from the manufacturing source?

19 A. That's correct. Unless the API is
20 available through their wholesaler.

21 Q. And what's a compounding pharmacy
22 wholesaler?

23 A. A wholesaler, in layman terms, is the
24 middleman.

25 Q. When you're searching for API, do you

1 generally contact your wholesaler first?

2 MR. SUTHERLAND: Object to the form.

3 You can answer.

4 THE WITNESS: Sure. It depends on the
5 product, the medication, and availability.

6 BY MS. NELSON-MAJOR:

7 Q. And if your wholesaler doesn't have a
8 particular API available, what do you do next?

9 A. You can try to find an actual manufacturer
10 that prepares APIs.

11 Q. And how do you find manufacturers?

12 A. There would be a database that's usually
13 associated with the wholesaler website. And so if
14 you type in, for example, the API active ingredient,
15 it could give you a list of any number of
16 manufacturers that potentially prepare this
17 worldwide.

18 Q. And when you search a database that you
19 just mentioned for API, do you have to specify that
20 you're looking for API versus commercially
21 manufactured drugs?

22 A. I'm not quite sure I understand. If
23 you're searching for API, that means the -- likely,
24 maybe the compounding pharmacist or pharmacy has
25 already tried to find a commercially manufactured

1 product.

2 Q. I'm going to pull up another Certificate
3 of Analysis. Hold tight for a moment. And we'll
4 e-mail this to you as well.

5 Can you see the document that I just pulled
6 up on your screen?

7 A. Yeah, it's pretty hard to read. I'll just
8 wait for the -- yeah, it'll be easier.

9 MR. SUTHERLAND: I'm still waiting for
10 it, Ms. Nelson.

11 MS. NELSON-MAJOR: Did that come
12 through to you yet, Mr. Sutherland?

13 MR. SUTHERLAND: It has not.

14 BY MS. NELSON-MAJOR:

15 Q. Dr. Patel, I'm not going to ask you about
16 any of the small print at the bottom of the page.
17 I'm really just looking at the top. So if you're
18 able to see that and are comfortable proceeding that
19 way, I'm fine. But if you'd rather wait, by all
20 means, we can wait.

21 A. If you can make it large, that would help.
22 Okay.

23 Q. Is that better?

24 A. Much better, yes.

25 Q. Have you seen this document before?

1 A. Yes.

2 Q. And it says, "CERTIFICATE OF ANALYSIS" at
3 the top?

4 A. That's correct.

5 Q. And it looks like it says it has a
6 manufacturing date of February 1, 2016?

7 A. That's correct.

8 Q. I'm going to mark this as Exhibit 4. And
9 do you see under "CERTIFICATE OF ANALYSIS" it says,
10 "MIDAZOLAM, BP"?

11 A. That's correct.

12 Q. Does that indicate to you that this API
13 was subjected to British Pharmacopeia standards?

14 A. That is my understanding, yes.

15 Q. And so like the other Certificate of
16 Analysis, this document doesn't demonstrate that
17 this midazolam API is USP grade?

18 A. That's correct, it was not tested against
19 USP monograph.

20 Q. Does the fact that this API was subjected
21 to BP standards indicate to you that it was
22 purchased or manufactured by a British source?

23 A. Again based on my training and background
24 and experience, is that the manufacturer is likely
25 located in the UK.

1 Q. And when you say likely, are you
2 suggesting that there's another explanation for why
3 this was subjected to BP standards?

4 A. No, that's just based on my background,
5 training and experience, that's what I would assume.

6 Q. I'm going to take this down.

7 MR. SUTHERLAND: I just received this
8 and I'm going to forward it to Dr. Patel.

9 Q. Dr. Patel, would you like to take a look
10 at that Certificate of Analysis just to confirm your
11 prior statement?

12 A. That's correct, I can take a look at it
13 real quick, that's not a problem. That's correct.

14 MS. NELSON-MAJOR: And, Mr. Sutherland,
15 I know that you said you would like to take a
16 break at 11:00 o'clock your time, 12:00
17 o'clock our time. Are you fine with pushing
18 through until then? Or would you like to take
19 a break, Mr. Sutherland or Mr. Patel, at this
20 point?

21 MR. SUTHERLAND: Fine pushing through.
22 Dr. Patel, what's your preference? Are you
23 okay?

24 THE WITNESS: I'm fine.
25

1 BY MS. NELSON-MAJOR:

2 Q. And as I mentioned earlier, if at any
3 point you do need to take a break, just let me know,
4 and we'll be happy to accommodate that.

5 In your report you note that, "The
6 Pharmacist outlined the procedure for sending the
7 sample of the CSPs for testing in regard to
8 potency/strength and sterility as recommended by USP
9 standards."

10 Are sterility, potency and strength all of
11 the quality requirements that USP imposes on
12 testing?

13 MR. SUTHERLAND: Ms. Nelson-Major, if I
14 could interject. Could you refer Dr. Patel to
15 where you're --

16 MS. NELSON-MAJOR: Absolutely.

17 MR. SUTHERLAND: -- talking about?

18 BY MS. NELSON-MAJOR:

19 Q. Let's turn to page 12, the first full
20 paragraph. And I'll direct you to the sentence
21 again. It's the first sentence of the first full
22 paragraph on page 12. You wrote, "The Pharmacist
23 outlined the procedure for sending the sample of the
24 CSPs for testing in regard to potency/strength and
25 sterility as recommended by USP standards."

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1 And my question was, are potency and
2 sterility the only quality requirements recommended
3 by USP?

4 A. The additional one is endotoxin.

5 Q. What about pH? Does the USP require
6 compounded preparations to be tested for pH?

7 A. That's correct. But it's actually
8 outlined for sending the sample. They're only --
9 you only need to send it for, my understanding,
10 potency or strength, which is really identification,
11 sterility, and the presence of endotoxin, which,
12 again, as I mentioned, is a trigger for fever. The
13 pH is actually performed at the end of preparation.

14 Q. And what do you mean by, "the end of
15 preparation"?

16 A. After the compounded sterile prep, or CSP,
17 is completed, the pH testing is usually the last
18 thing done by the pharmacist or the technician.

19 Q. If a drug that you compounded failed one
20 of the required USP standards, would you release it
21 for use on a patient?

22 A. If the drug failed testing, no, it would
23 not be sent for use for a patient.

24 Q. Why not?

25 A. The reason is, is that -- it actually

1 depends on which standard failed as well. But for
2 the most part, the ones that end up flagging are
3 either potency or sterility. And the reason is, of
4 course, potency could be less concentrated or more
5 concentrated than what was prescribed. And
6 sterility and/or endotoxin have to do with the
7 presence of bacteria, which means there could be a
8 risk of infection hours or days after
9 administration.

10 Q. And if when you tested a CSP for pH and it
11 was outside the acceptable range, would you release
12 that to a patient?

13 A. If the pH was outside the range, it would
14 not be released, because the pH has to do with the
15 stability and solubility of the CSP.

16 Q. What about if you didn't get a pH test
17 result back, would you release that drug for use on
18 a patient?

19 A. If we didn't get a pH test back. Well,
20 the CSP isn't sent for pH, the CSP is -- the pH, as
21 I mentioned, is done right after preparation, then
22 the CSP, from at least my understanding, is sent
23 out.

24 Q. My question is, if you in a clinical
25 setting tested a final preparation for pH, but for

1 some reason the results were lost, would you still
2 nonetheless release that drug for use on a patient?

3 A. If the pH result was lost, no, we would
4 not release it for patient care.

5 Q. Why not?

6 A. Again, because it has to do with the
7 stability or solubility of the actual preparation.
8 The reason that this is critical is that many of
9 these things are stored long term and so the
10 stability and/or solubility are important, which is
11 why the pH testing is done.

12 Q. Does pH have any impact on how the drug
13 feels to a patient when it's administered?

14 A. Not to my understanding, no. The actual
15 proper use of pH is, again, stability and
16 solubility. Drug administration, the only time I'm
17 aware of pH being a factor is actually if it
18 extravasates, which, if you're familiar with the
19 term, meaning the drug getting outside the vein.

20 As long as the drug is in the vein, an
21 antecubital large vein, which I believe a
22 antecubital fossa is utilized, it is not an issue.
23 And the reason, again, it's my opinion, is if we
24 look at a number of -- just take anesthetic drugs,
25 the pH's go as far as two and as high as nine.

1 So if what you just stated was actually
2 scientifically and methodologically true, we
3 wouldn't have any drugs to use for patient care.

4 Q. And so the only reason pH is tested on a
5 final product is for long-term stability concerns?

6 A. That is the two main reasons, that's
7 correct, of utilizing and testing for pH of a CSP.
8 Injection upon pain site is not a reason that you're
9 testing for pH, as I already described.

10 Q. And so you could inject a prepared drug
11 into a patient's peripheral IV regardless of the pH
12 of that final product.

13 A. The injection pH, again, it's more of a
14 concern -- or really any concern if the drug
15 extravasates; meaning, it gets outside the vein.
16 So, for example, Dilaudid, hydromorphone, has a pH
17 identical to midazolam, between about two and three.
18 Phenobarbital, as an example, has a pH between nine
19 and ten. So if that scientific methodology was
20 true, we wouldn't have any drugs to inject in
21 patients. So, no, it's not an issue.

22 Q. And the risk of -- and excuse me if I get
23 this word wrong -- extravasation, which is
24 essentially leakage outside of the vein, does that
25 concern factor into the way that pH is adjusted in

1 the lab setting?

2 A. It would only be applicable to drugs with
3 a pH of, my understanding, less than five or greater
4 than nine, which is pretty much virtually everything
5 we use in patient care.

6 Q. Returning to the LIC that's compounded for
7 TDOC. Was all of the LIC that was prepared by the
8 compounding pharmacy in fact subjected to the
9 required tests under USP?

10 MR. SUTHERLAND: Object to the form.

11 You can answer.

12 THE WITNESS: Sure. My understanding
13 is, again, the -- from what I have -- we have
14 available, the identification and potency was
15 tested, the sterility was tested; however, the
16 endotoxin test, as I had mentioned, was
17 absent.

18 BY MS. NELSON-MAJOR:

19 Q. And you've seen documentation that
20 sterility test was performed on all the compounded
21 preparations that you've seen documentation of?

22 A. I've seen the testing performed on
23 midazolam and/or potassium chloride, which have, of
24 course, associated potency or strength and/or
25 sterility tests. And we have to also kind of think

1 about how the tests are performed, which wasn't
2 discussed in any of the reports. Generally, it's a
3 sequence.

4 So, for example, the potency and/or
5 sterility are performed. The endotoxin, from my
6 understanding, is an incubation. So that's why the
7 dates are all different. And for some reason the
8 dates are sometimes even seven to ten days apart, as
9 they should be, because the incubation time is
10 generally about -- within about a two-week time
11 period.

12 Q. And you've seen reports from the lab
13 documenting the results of endotoxin testing on the
14 drugs compounded for TDOC?

15 A. There are endo-- there is endotoxin
16 testing with, I believe, at least one midazolam
17 sample. And I can't recall if it was done with
18 potassium chloride. But it was performed. And as I
19 had mentioned and stated, I didn't see it with every
20 testing certificate that was provided.

21 Q. It's your understanding that those tests
22 that were performed were performed on CSPs and not
23 final products for use by TDOC?

24 A. Well, the -- my understanding -- and I'm
25 using CSP is the final product.

1 Q. You mentioned sterility, endotoxin, and
2 potency. Do you see test results for any other
3 quality requirements set forth in the USP?

4 A. Those are the three according to 797 which
5 are required that the pharmacy send out prior to
6 sending it to the end user.

7 Q. Do you know the methodology that the labs
8 used to conduct each of those tests that you've seen
9 results for?

10 A. The methodology they used, again, are in
11 accordance with USP. So, for example, sterility is
12 associated with USP 71; endotoxin, for the one
13 certificate I did see it on, is in accordance with,
14 if I recall correctly, USP 85; and the
15 identification is an assay done by high-performance
16 gas-liquid chromatography, which gets you a
17 percentage. And the acceptable range, as I stated
18 in my report, is plus or minus ten percent.

19 Q. I'm just pulling up a document. And you
20 previously testified that you reviewed Dr. Almgren's
21 report in this case; is that right?

22 A. I reviewed -- that's correct, I reviewed
23 the first report and a rebuttal that was submitted,
24 I thought around mid-January.

25 Q. And as you will recall, Dr. Almgren

1 identified a number of testing results that she
2 believed were missing. Do you recall that?

3 A. I do, yes.

4 MR. SUTHERLAND: I'm going to object to
5 the form and ask that you refer him to
6 specific things in her report if you're going
7 to talk about it.

8 MS. NELSON-MAJOR: I'm going to pull up
9 Dr. Almgren's report. And we'll send a copy
10 of that to you as well.

11 MR. SUTHERLAND: Thank you. Dr. Patel,
12 I'll forward this to you as soon as I get it.

13 THE WITNESS: No problem.

14 MS. NELSON-MAJOR: I'm going to wait,
15 instead of trying to get you to take a look at
16 the screen, because the font is small on this
17 document.

18 MS. LEONARD: I just e-mailed it. So
19 hopefully it's not a long delay this time.

20 MR. SUTHERLAND: Just got it and I just
21 forwarded it.

22 BY MS. NELSON-MAJOR:

23 Q. And while you're pulling that up, Dr.
24 Patel, I'm just going to mark for the record
25 Dr. Almgren's report as Exhibit 5.

1 A. Okay.

2 Q. And I'm looking at paragraph 35, which
3 begins on pdf page 13, I believe.

4 A. One second. The pdf is still pulling up.
5 Oh, shoot, I lost it. You said page 13?

6 Q. Paragraph 35 begins on page 13 of the pdf
7 and then continues on to the next page. I'm sorry,
8 begins on page 12 and continues on to page 13.

9 A. There we go. Okay. I have it.

10 Q. Okay.

11 A. Making it larger.

12 Q. So you reviewed this bulleted list in
13 which Dr. Almgren reviews the available
14 documentation of the test results that were
15 performed on midazolam compounded for TDOC?

16 A. That's correct.

17 Q. And in each bullet point Dr. Almgren looks
18 at a separate CSP compounded for TDOC and notes the
19 test results that were reported on the documents; is
20 that right?

21 A. That's correct.

22 Q. And you also reviewed the test results
23 that were provided for the midazolam compounded for
24 TDOC?

25 A. I have, yes.

1 Q. Dr. Almgren identifies a number of tests
2 that were not performed on each one of these batches
3 of midazolam compounded for TDOC. For example, I'm
4 looking at the first bullet point, which is for a
5 midazolam sample submitted on September 22 of 2018,
6 there was an assay and sterility test reported, but
7 no other test results were available. Do you see
8 that?

9 A. The first one? Yes, I do.

10 Q. In your review of the records, did you see
11 any other test results reported for that midazolam
12 sample?

13 A. For that one? No, I did not.

14 Q. If you had compounded midazolam for
15 patient use in a clinical setting and had only
16 received an assay and a sterility test result, would
17 you release that sample for use on a patient?

18 A. For the CSP? No, we would have to wait
19 for endotoxin results to return.

20 Q. And if you then took this CSP and prepared
21 it for final preparation and use on a patient, what
22 other tests would you have to perform?

23 A. The only one is, as I had mentioned, is
24 endotoxin. Again, that's testing for pieces of dead
25 bacteria that can trigger a fever.

1 Q. You wouldn't test it for pH prior to
2 patient release?

3 A. Prior to patient release it is not tested
4 for pH. pH is tested prior to sending it for the
5 sterility and potency evaluation.

6 Q. So this particular midazolam sample you
7 would not release until it had been tested for pH
8 and endotoxins in a clinical setting; is that right?

9 A. The pH is done prior to its being sent, so
10 it's the last step in actual physical preparation.
11 And, correct, the endotoxin would be due to the risk
12 of fever, which, again, could be potentially present
13 hours to days after administration. That's correct.

14 Q. And then I'm going to ask you to turn to
15 paragraph 37 of Dr. Almgren's report. Excuse me,
16 paragraph 38.

17 A. Okay.

18 Q. So as with midazolam, Dr. Almgren reviewed
19 the records of test results performed on the
20 potassium chloride compounded for TDOC. In your
21 review of the records of the test results, did you
22 see other results of testing performed on potassium
23 chloride that Dr. Almgren failed to include in her
24 report?

25 A. I have not, no.

1 MR. SUTHERLAND: Object to the form.

2 BY MS. NELSON-MAJOR:

3 Q. Looking at the second bullet point in
4 paragraph 38, it states that potassium chloride
5 received on August 6 of 2019 was tested for assay
6 and failed with a potency of 94 percent. There was
7 no indication that it had been tested for sterility.

8 In that case, would you have released that
9 sample for patient use?

10 A. No. And it's not because it didn't pass
11 potency. Right? Remember, potency is plus or minus
12 ten percent. So it actually passes potency. But
13 there is not a sterility or endotoxin testing and
14 that's why it's actually failed.

15 Q. I want to ask you about that potency
16 quality requirement in a moment, but just to close
17 the loop on this. In your clinical practice, do you
18 document the test results for the compounded
19 preparations that you prepare?

20 A. No, there is no documentation, because
21 your documentation is the analysis that was
22 performed when it was sent out.

23 Q. By a lab?

24 A. That's correct, it would be an independent
25 laboratory.

1 Q. Does the independent laboratory provide
2 you with documentation of the test results?

3 A. That's correct. And that's what I believe
4 we've been reviewing.

5 Q. And do you maintain records of those test
6 results in any way in your pharmacy?

7 A. No. After they're verified and confirmed,
8 they're not really of any -- of any need.

9 Q. I want to turn to your report again, and
10 we're going to look at page 12. Let me know when
11 you're there.

12 A. Okay.

13 Q. I'm looking at that first full paragraph
14 again, the second sentence, which begins, "The
15 accepted standard." Do you see where I am?

16 A. It's on page 12. And which paragraph and
17 sentence are you referring to?

18 Q. The first full paragraph. It's the
19 paragraph that begins, "The Pharmacist outlined."

20 A. I see that, yes.

21 Q. Okay. Now I'm looking at the second
22 sentence, excuse me, which states, "The accepted
23 standard by USP for label strength is within 10
24 percent and prepared to maintain sterility until the
25 beyond use date. Meaning the acceptable potency is

1 between 90 [to] 110 percent."

2 Is the 90 to 110 percent that you identify
3 there true for all compounded preparations?

4 A. That's correct, under the recommendations
5 of USP.

6 Q. And the USP monograph for a particular
7 drug doesn't set a separate potency standard?

8 A. That's incorrect. So, for example, if you
9 pull up the monograph for USP in terms of the API,
10 it's identical to the EP and BP. The plus or minus
11 ten percent, so it's not confused, it applies to the
12 finished CSP which was sent for testing. Those are
13 two different things.

14 Q. The question I'm asking about is the CSP.
15 Do the USP monographs for CSPs, or compounded
16 preparations, vary from drug to drug?

17 A. I don't understand your question. The
18 monograph applies to APIs. The standard for USP for
19 compounded sterile preparation, or CSPs, is always
20 plus or minus ten percent. So I don't understand
21 the question, it doesn't make sense to me. I
22 apologize.

23 Q. No, that's fair. I'm going to pull up
24 another exhibit, and we'll e-mail that to you, it's
25 a USP monograph for potassium chloride. And I'm

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1 going to wait until you receive this, so you can
2 read it more clearly.

3 MR. SUTHERLAND: I just forwarded it to
4 you, Dr. Patel.

5 A. I got it. Okay. Thank you.

6 Q. Do you see at the top of this page it
7 says, "Potassium Chloride for Injection
8 Concentrate"?

9 A. I do, yes.

10 Q. Have you seen this document before?

11 A. I have, yes.

12 Q. And what is it?

13 A. This appears to be the copy that was
14 printed in regards to potassium chloride concentrate
15 in accordance with USP. It appears to be a
16 monograph.

17 Q. And I'm looking at the paragraph right
18 under the heading I just directed you to. Do you
19 see where it states, "It contains not less than
20 95 percent and not more than 105 percent of the
21 labeled amount of KCl"?

22 A. That's correct.

23 Q. Is that a potency requirement for
24 potassium chloride for injection concentrate?

25 A. That would be the potency for a bulk

1 package, or API, that's correct.

2 Q. Excuse me, I'd like to mark this as
3 Exhibit 6. I neglected to do that.

4 So does that mean when the potassium
5 chloride is subjected to potency testing, that it
6 needs to be within 95 and 105 percent of the labeled
7 amount of KCl?

8 A. For potassium chloride, that's correct.

9 Q. And is that different than the 90 to
10 110 percent range you noted in your report?

11 A. That's correct.

12 Q. I'm going to pull up a test report for a
13 batch of potassium chloride that was compounded for
14 TDOC, and we'll e-mail this to you as well. I've
15 also pulled it up on the screen.

16 MR. SUTHERLAND: I just got it and I'm
17 forwarding it now.

18 Q. Do you have that document, Dr. Patel?

19 A. Yeah, it's pulling up. Give me just a
20 second. Okay.

21 Q. Is this a document that you've previously
22 reviewed?

23 A. If it was with the associated testing
24 reports then, yes.

25 Q. It's a laboratory report for potassium

1 chloride and it has date received July 16, 2019. Do
2 you see that?

3 A. I do, yes.

4 Q. I'm going to mark this as Exhibit 7.
5 There's two test results reported on this document.
6 What was the number reported for potency?

7 A. For this batch that was sent for testing,
8 it was 112 percent.

9 Q. And what does 112 percent mean in this
10 context?

11 A. It's 112 percent, 12 percent stronger than
12 the 2 mil equivalent per mL.

13 Q. So this preparation does not meet the USP
14 standards for potency for potassium chloride; is
15 that right?

16 A. For testing, for the recommended 95 to
17 105 percent, that's correct, this would not pass.

18 Q. It also doesn't pass that other 90 to
19 110 percent range that you noted in your report; is
20 that correct?

21 A. That's correct.

22 Q. If you received a report indicating that a
23 drug had exceeded the acceptable potency range,
24 would you release it for use?

25 A. For use in patient care, no.

1 Q. So we just looked at that USP monograph
2 which states the acceptable range between 95 and
3 105 percent for potassium chloride. Why did you
4 state that the acceptable range for both drugs was
5 98 to 110 percent in your report?

6 A. In clinical practice, plus or minus ten
7 percent is virtually used for compounded
8 medications. The USP has recommendations of a
9 specific range for different chemicals or
10 preparations that are compounded individually. And
11 plus or minus ten percent is what is used
12 clinically.

13 Q. And if the USP specifies a different range
14 for a particular drug, do you follow that different
15 range or do you follow the general range when
16 compounding a preparation?

17 A. No, you would default to the USP
18 recommendations in the setting of inpatient patient
19 care.

20 Q. All right. I'm going to pull up a
21 different test result report, and we'll e-mail that
22 to you as well.

23 When you were drafting your report, did you
24 consult the USP monographs for midazolam and
25 potassium chloride?

1 A. Did I consult them? No. Did I review
2 them? Yes.

3 MS. NELSON-MAJOR: Let me know when
4 you've received that, Mr. Sutherland.

5 MR. SUTHERLAND: Just sent it.

6 MS. NELSON-MAJOR: Thank you.

7 THE WITNESS: Okay. I have it.

8 BY MS. NELSON-MAJOR:

9 Q. This is another lab report for potassium
10 chloride, with a date received August 6, 2019. Is
11 this a lab report that you've also reviewed before?

12 A. If it was within associated documents,
13 that's correct.

14 Q. I'm going to mark this lab report as
15 Exhibit 8. What is the potency result reported for
16 this batch of potassium chloride compounded for
17 TDOC?

18 A. It's 94 percent.

19 Q. And, again, what does 94 percent mean in
20 this context?

21 A. Just as stated, instead of 2 mil
22 equivalent per mL, it's 1.88 mil equivalent per mL.

23 Q. If you received this report for a batch of
24 potassium chloride that you compounded, would you
25 release it?

1 A. Since you default to 95 to 105, no, you
2 would not, for patient care.

3 Q. I'm next going to pull up the USP
4 monograph for midazolam. If you hang tight, we'll
5 e-mail that to you as well.

6 MR. SUTHERLAND: On its way.

7 A. Okay.

8 Q. Have you seen this document before?

9 A. I have, yes.

10 Q. And what is it?

11 A. It's the associated monograph for
12 midazolam.

13 Q. And there's -- I've highlighted a sentence
14 in the first paragraph of the definition, which
15 states, "It contains the equivalent of NLT" --
16 meaning, I'm assuming, not less than -- "90 percent
17 and NMT" -- meaning not more than -- "110 percent of
18 the labeled amount of midazolam."

19 Is that the acceptable potency range set
20 for midazolam?

21 A. That's correct, it's plus or minus ten
22 percent.

23 Q. I'm going to pull up a test result, and
24 we'll e-mail that to you as well. Let me know when
25 you receive that.

1 MR. SUTHERLAND: On its way.

2 MS. NELSON-MAJOR: Thank you.

3 A. Okay.

4 Q. And have you seen this lab report before?

5 A. If it was within the documents and what's
6 cited, yes, I likely have.

7 Q. So it's a lab report for midazolam with a
8 date received of November 13, 2019. I'm going to
9 mark that as Exhibit 10.

10 And what is the potency result reported for
11 this batch of midazolam?

12 A. The potency as stated as tested is
13 114 percent.

14 Q. Meaning it was 14 percent higher than the
15 intended potency?

16 A. Four percent above the acceptable limit,
17 that's correct.

18 Q. My question was, was it 14 percent of the
19 intended volume of midazolam specified for this --
20 that was a terrible question, let me try restating
21 that for you.

22 The potency measures the actual amount of
23 midazolam in the compounded preparation versus the
24 intended amount of midazolam; is that correct?

25 A. That's correct.

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1 Q. And so this compounded preparation had
2 14 percent more midazolam than the target amount of
3 midazolam the pharmacy intended; is that correct?

4 A. That's correct, a total of seven
5 milligrams per mL more.

6 Q. So this compounded midazolam does not meet
7 the acceptable potency range set by USP; is that
8 right?

9 A. That's correct, it's four percent above.

10 Q. And if you had received this report for
11 midazolam that you had compounded, would you have
12 released it?

13 A. No, we would not have released it for
14 patient care.

15 Q. You reviewed the deposition of the
16 pharmacist who supplies TDOC with lethal injection
17 drugs, correct?

18 A. I did review that deposition, that's
19 correct.

20 Q. And so you're aware that the compounding
21 pharmacy sent CSPs to a third-party lab for testing?

22 A. That was my understanding based on their
23 standard operating procedure, that's correct.

24 Q. And you're also then aware that that
25 third-party company had been issued a violation

1 letter by the FDA?

2 A. That they've been issued a violation
3 letter by the FDA? No, I'm not familiar. But I'm
4 also not surprised.

5 Q. So you don't recall that the pharmacist
6 testified that the testing company that they had
7 contracted with had been issued a violation letter?

8 A. No, I don't recall that exact sentence or
9 that the pharmacist testified to that.

10 Q. Why do you say that you're not surprised?

11 A. For any that are in the healthcare,
12 especially the compounding, industry are familiar
13 with virtually any infraction, whether it would be
14 during preparation, testing, or any part of the
15 process, there is a subject and a risk of error or
16 something going wrong. And so whether it's a small
17 pharmacy or a large manufacturer; for example,
18 Nephron, nobody's devoid of any infractions of
19 citations. So I'm not surprised.

20 Q. So, in your opinion, have most third-party
21 testing labs been issued FDA violation letters?

22 A. It's not that most have been issued, it's
23 the fact that any person, whether it's a individual
24 pharmacy or a large 503B manufacturer, at some point
25 is going to have an infraction on the testing or

1 analysis or their policy and procedure once
2 inspected.

3 So, no, I'm not surprised they've been
4 issued an FDA letter. In fact, most of our 503Bs
5 that are available to us here in the U.S., there's
6 not a single one that I'm aware of that doesn't have
7 an infraction letter, inclusive of Nephron.

8 Q. And I'm specifically asking about third-
9 party testing companies, not 503B manufacturers.
10 Would what you just stated also be true about third-
11 party testing companies?

12 A. That's correct. But you have to recall,
13 that in order to be subjected to a violation, they
14 have to register and undergo an evaluation. So just
15 because it's a third-party testing laboratory
16 doesn't automatically assume they're always going to
17 get inspected or when they do. So that's why I
18 mention I'm not surprised.

19 Q. Do you know the nature of the violation
20 that caused the FDA to issue the letter to the
21 third-party testing company that the compounding
22 pharmacy uses?

23 MR. SUTHERLAND: Objection to the form.

24 THE WITNESS: I do not know the nature
25 of the letter, nor have I seen it, no.

1 BY MS. NELSON-MAJOR:

2 Q. So you're not aware if it's a minor
3 violation or something more serious?

4 A. No. But from my background, training and
5 experience, if it's serious, that generally shuts
6 down a facility or a company or a testing area for a
7 prolonged period of time.

8 MS. NELSON-MAJOR: Mr. Sutherland, I'm
9 at a good stopping point. I know that you had
10 wanted to stop at this point, so maybe that
11 makes sense.

12 MR. SUTHERLAND: Yeah, this is a good
13 time. Maybe come back at 11:30, if it's all
14 right. I'm sorry, 11:30 Central, 12:30
15 Eastern.

16 MS. NELSON-MAJOR: I understood you.
17 Dr. Patel, does that work for you?

18 THE WITNESS: Yeah, that's fine for me,
19 not a problem.

20 MS. NELSON-MAJOR: Okay.

21 MR. SUTHERLAND: Thank you very much.

22 VIDEOGRAPHER: Going off the record,
23 the time is 10:58.

24 (A brief recess was taken.)

25 VIDEOGRAPHER: Back on the record, the

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1 time is 11:31.

2 BY MS. NELSON-MAJOR:

3 Q. Dr. Patel, did you talk to anyone during
4 that break?

5 A. No, I did not.

6 Q. I'm going to direct you back to your
7 report, page 12, if you want to pull it up.

8 A. Okay.

9 Q. I'm looking at the paragraph on the bottom
10 of the page, which starts, "Once the pharmacy is
11 ready to ship the CSPs (midazolam and potassium
12 chloride) and vecuronium it is packaged in dry ice
13 with a temperature gauge device to facilitate safe
14 transport..."

15 Are all three of the drugs to be shipped on
16 dry ice?

17 A. No, the vecuronium is room temp, the midaz
18 and potassium chloride is dry ice.

19 Q. And what is the temperature gauge device
20 that you reference?

21 A. If I recall correctly, the pharmacist
22 described -- and there's a number of proprietary
23 products. But if I recall correctly, it was a
24 mechanism which had a blue dot to signify that the
25 packaging box in itself was within range during

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1 transport.

2 Q. And how does that temperature gauge device
3 facilitate safe transport of the LIC to TDOC?

4 A. It's pretty standard operating procedure
5 that if you receive it from anybody preparing CSPs,
6 that there is a mechanism of some sort, because the
7 -- one of the most important things is the
8 temperature during transport.

9 Q. What would happen if the recipient was
10 unaware that the package contained a temperature
11 gauge device?

12 MR. SUTHERLAND: Object to the form.
13 You can answer.

14 THE WITNESS: If the recipient is
15 unaware that a temperature gauge device?

16 MS. NELSON-MAJOR: Uh-huh. That was my
17 question.

18 THE WITNESS: Well, if there wasn't a
19 temperature gauge device, then they wouldn't
20 know, for example, for CSPs that require
21 either a refrigerator, or in this case a
22 freezer, if it was within range during
23 transport.

24 BY MS. NELSON-MAJOR:

25 Q. And you reviewed the deposition of the

1 drug procurer. That's correct?

2 A. That is correct, yes.

3 Q. And so you're aware that, according to the
4 drug procurer, the dry ice shipments from the
5 pharmacy do not contain a temperature gauge device?

6 MR. SUTHERLAND: Object to the form.
7 You can answer.

8 THE WITNESS: Based on what the
9 pharmacist, I believe, testified to, and I
10 believe that it was labeled pharmacy owner,
11 that is their standard procedure for shipping
12 CSPs that are frozen.

13 BY MS. NELSON-MAJOR:

14 Q. And from reviewing the drug procurer's
15 deposition, you're aware that the drug procurer is
16 the person who receives the drugs at TDOC?

17 A. That is my understanding, yes.

18 Q. And if the drug procurer is unaware that
19 there's a temperature gauge device in the box, is
20 the drug procurer able to assess whether the
21 temperature went out of range during shipment?

22 MR. SUTHERLAND: Object to the form.
23 You can answer.

24 THE WITNESS: If that mechanism or
25 device the pharmacist and pharmacy owner had

1 described was not in place then, no, the drug
2 procurer would not know that.

3 BY MS. NELSON-MAJOR:

4 Q. And in that case, obviously, the
5 temperature gauge device couldn't ensure safe
6 transport of the LIC to TDOC, correct?

7 A. As for the required temperature, that's
8 correct.

9 Q. And then continuing on onto page 13 of
10 your report, you note that TDOC stores the LIC in a
11 fridge/freezer that has a temperature probe monitor
12 on the outside to "track the temperature." What do
13 you mean by "track the temperature"?

14 A. It's a monitor that tells you what the
15 temperature is inside the container.

16 Q. Does the probe send an alert if the
17 temperature goes above or below a certain range?

18 A. Not to my knowledge, no. Nor is it
19 required.

20 Q. Does it record the temperature at a given
21 interval?

22 A. From my understanding and review of the
23 records, no. Nor is it required.

24 Q. And what do you mean when you say, "Nor is
25 it required"?

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1 A. Just as I stated, if you go to USP page
2 29, it'll actually identify the requirements for the
3 recipient. In this case, that would be TDOC.

4 MS. NELSON-MAJOR: I'm going to pull up
5 a document that we will -- I believe was
6 already sent to you over the break,
7 Mr. Sutherland, some photographs. And I'm
8 also pulling them up on my screen.

9 MR. SUTHERLAND: I just forwarded them.

10 THE WITNESS: Okay.

11 BY MS. NELSON-MAJOR:

12 Q. Are these the photographs that you cited
13 in your report of the fridge and freezer?

14 A. I believe these are it, yes.

15 Q. I'm going to mark these photographs as
16 Exhibit 11. Does this mini fridge have a separate
17 freezer and refrigerator compartment?

18 A. From my -- from looking at the photograph,
19 my understanding, yes, the top was the freezer and
20 the bottom's the fridge.

21 Q. And in your report you note that the
22 compounded preparations are stored in the freezer
23 but are later moved to the fridge to thaw prior to
24 an execution. Is that your understanding?

25 MR. SUTHERLAND: Ms. Nelson-Major, when

1 you refer to his report, will you please
2 direct him to where you're talking about, just
3 so there's no misunderstanding? I'm sorry.

4 Q. So, Dr. Patel, we're still on page 13,
5 still on that paragraph that I pointed you to, and
6 you write, "Once received by TDOC, the LICs are
7 stored in a separate building, secured via a steel
8 lock on the fridge and freezer..."

9 And then scrolling down to page 13, the
10 first full paragraph, the first sentence, you write,
11 "Once TDOC is ready to administer the LIC, the CSPs
12 are removed from the freezer (negative 25 degrees to
13 negative 10 degrees C) and placed into the
14 refrigerator as instructed to allow the medication
15 to thaw.

16 And in this paragraph of your report you
17 reference a temperature range for the freezer and
18 refrigerator. What are those temperature ranges?

19 A. They're the ones in the report.

20 Q. And what are those temperature ranges?

21 A. For the freezer it's a range of minus 25
22 to minus 10, and in the fridge it's 2 to 8
23 centigrade.

24 Q. And where do you get these temperature
25 ranges from?

1 A. A couple of places. One is my house and
2 the second is USP.

3 Q. What do you mean you got those temperature
4 ranges from your house?

5 A. That's what the manual says on the fridge.

6 Q. So these temperature ranges, are you
7 citing the manual for your fridge at your house or
8 the USP guidance for storage?

9 A. They're two of the same.

10 Q. Turning back to Exhibit 11, the pictures
11 of the fridge. Did you see the manual for this mini
12 refrigerator in discovery?

13 A. Did I see the manual? No, I didn't see
14 the actual manual. I see it's Frigidaire, in terms
15 of the brand.

16 Q. So you don't know whether this fridge has
17 the same temperature ranges as your refrigerator at
18 home?

19 A. No, I don't know if it's the exact same
20 range. But the probe on the outside tells us.

21 Q. And taking a look at the probe on the
22 outside, have you seen this type of probe before?

23 A. Have I seen that type of probe? No, I've
24 never seen that type of probe before.

25 Q. Does the temperature monitor on the

1 outside of this refrigerator read the temperature in
2 the fridge compartment or the freezer compartment?

3 MR. SUTHERLAND: Object to the form.

4 You can answer.

5 THE WITNESS: Sure. My understanding
6 is, it's reading the refrigerator compartment.

7 BY MS. NELSON-MAJOR:

8 Q. And why is that your understanding?

9 A. Based on the temperature that's listed
10 there in centigrade. Or, I'm sorry, in Fahrenheit.

11 Q. And what is the temperature that's listed?

12 A. I thought it was 36.9 or -- if I remember
13 right.

14 Q. I'm going to scroll to the second page,
15 where there's a closer view of the monitor. And
16 what about the fact that it's 39-- excuse me, 36.9
17 Fahrenheit leads you to believe that the temperature
18 probe is in the fridge compartment?

19 A. Because if you equate that to Celsius, it
20 would fall within range, if I remember right.

21 Q. And what is 36.9 in Celsius?

22 A. I can do the calculation. I didn't do it
23 off the top of my head.

24 Q. No, Dr. Patel, that's fine, I'm not asking
25 you to do the calculation. It sounded like at one

1 point you perhaps had done the calculation and
2 that's why I was asking.

3 Do you see in the bottom left corner of the
4 monitor there's a large X?

5 A. Yes.

6 Q. And on the yellow perimeter of the monitor
7 below that large X, do you see where it says, "Alarm
8 state"?

9 A. I do, yes.

10 Q. And then below "Alarm state" there is a
11 checkmark with an equals sign to "OK"?

12 A. That's correct.

13 Q. And then below that there's a large X with
14 an equals sign to the word "ALARM"?

15 A. That's correct.

16 Q. Does the X on the screen indicate that the
17 temperature readings have triggered some sort of
18 alarm?

19 MR. SUTHERLAND: Object to the form.
20 You can answer.

21 THE WITNESS: If it triggered an alarm?
22 Well, it looks like it's an X. But I don't
23 know if that's because a picture was taken or
24 if it triggered an alarm. So I actually can't
25 say.

1 BY MS. NELSON-MAJOR:

2 Q. Do you know what range TDOC sets that
3 monitor to as far as temperature?

4 A. Do I know what range it set it to?

5 Q. Yes.

6 A. No, I can't tell by looking at this. No.

7 Q. And at the top of the monitor, do you see
8 a series of triangles?

9 A. I do, yes.

10 Q. And above that series of triangles on the
11 perimeter of the monitor there's a series of striped
12 markings?

13 A. If you're referring to the triangles, yes.

14 Q. And the first striped marking starting
15 from the right-hand corner says, "today." Do you
16 see that?

17 A. That's correct.

18 Q. And then the next striped marking says,
19 "yesterday"?

20 A. That's correct.

21 Q. And then the next one says, "minus 2d"?

22 A. Correct.

23 Q. Does it appear that "minus 2d" means two
24 days ago, given the sequence?

25 MR. SUTHERLAND: Object to the form.

1 You can answer, if you know.

2 THE WITNESS: I don't know, no.

3 BY MS. NELSON-MAJOR:

4 Q. Do you see that after minus 2d, it goes
5 minus 3d, minus 4d, minus 5d, all the way up to
6 minus 29d?

7 A. That's correct. I see that.

8 Q. Are you aware that each triangle indicates
9 that the probe recorded a temperature outside of a
10 specified range on the day indicated on the striped
11 marking on the perimeter?

12 MR. SUTHERLAND: Object to the form.

13 You can answer.

14 THE WITNESS: No, I'm not aware of
15 that. No.

16 BY MS. NELSON-MAJOR:

17 Q. And you weren't provided with a copy of
18 the user manual for this temperature probe, were
19 you?

20 A. I do not have a --

21 MR. SUTHERLAND: Object to the form.

22 You can answer.

23 THE WITNESS: Oh, sorry. No, I don't
24 have a manual, so I can't comment.

25

1 BY MS. NELSON-MAJOR:

2 Q. How often does TDOC check the temperature
3 gauge?

4 MR. SUTHERLAND: Object to the form.
5 You can answer.

6 THE WITNESS: How often do they check
7 the temperature gauge that's storing the LICs?

8 MS. NELSON-MAJOR: Correct.

9 THE WITNESS: I don't know how often
10 they check it.

11 BY MS. NELSON-MAJOR:

12 Q. Do you know when TDOC installed this
13 temperature gauge?

14 A. I do not know, no.

15 Q. Do you know what action TDOC would take if
16 an alert was sounded on the temperature gauge?

17 MR. SUTHERLAND: Object to the form.
18 You can answer.

19 THE WITNESS: I do not know, no.

20 BY MS. NELSON-MAJOR:

21 Q. I'm going to turn back to your report, if
22 you could pull that up, please.

23 A. Okay.

24 Q. And I'm going to ask you to look at page
25 three.

1 A. Okay.

2 Q. And I'm looking at the heading: Materials
3 Reviewed and Relied Upon. Why didn't you include
4 the photographs of the mini fridge on this list?

5 A. Why didn't I include them? Because they
6 were one of the produced exhibits. But I cited it.
7 So I guess I don't understand. Why isn't it listed
8 twice is what you're asking?

9 Q. No, I'm asking you why these documents --
10 these photographs don't appear on this list.

11 A. Oh, I see what you're saying. I felt it
12 was redundant. So I cited it within the report,
13 which it should be.

14 Q. Are there other documents that you
15 reviewed and relied upon but didn't either cite in
16 section three or elsewhere in the report?

17 A. If it's cited, then if it's not in that
18 section three, then I would imagine it probably
19 is, I don't know. I just felt it was redundant, so
20 I didn't include it in two places.

21 Q. I don't think my question was clear. Let
22 me try again. So you're saying every document that
23 you have reviewed and relied upon is either cited in
24 this section or in the body of your report; is that
25 right?

1 A. Affirmative.

2 Q. Are there other documents that are not
3 cited in this section or the body of your report
4 that you reviewed and relied upon?

5 A. I don't believe so. They should all be
6 contained within the report, unless they were
7 materials I was provided, like I mentioned in the
8 beginning, thereafter.

9 Q. Did you read the deposition of the
10 executioner?

11 A. I did, yes.

12 Q. Are you aware that when asked to describe
13 how he follows aseptic techniques when preparing the
14 syringes, the executioner said that he cleans the
15 needle with an alcohol wipe? Do you recall reading
16 that?

17 A. I recall that, that's correct.

18 Q. Is wiping the needle with an alcohol wipe
19 consistent with aseptic technique?

20 A. It is not consistent with aseptic
21 technique within a patient care setting.

22 Q. Does aseptic technique vary based on the
23 setting in which the procedure is being performed?

24 A. According to the recommendations, aseptic
25 technique was originally asserted and defined in the

1 setting of diagnosis, care, treatment, and healing.
2 So, yes, it does vary.

3 Q. Is your --

4 A. Different? Yes, it is different than what
5 is recommended.

6 Q. And, I'm sorry, Dr. Patel, I thought you
7 were pausing because you were finished. My
8 apologies.

9 Is it your opinion that the aseptic
10 technique that the protocol requires TDOC to follow
11 during an execution is different than standard
12 aseptic technique in a clinical setting?

13 MR. SUTHERLAND: Object to the form.
14 You can answer.

15 THE WITNESS: For the purposes of the
16 end user, they followed the instructions as
17 provided by the pharmacy. Is using a alcohol
18 swab on a needle different than what's
19 recommended, that's correct. Does it
20 introduce a risk that is subjected, that's
21 correct, and I believe it's negligible. But
22 it is different, that is correct.

23 BY MS. NELSON-MAJOR:

24 Q. Is the needle sterile before it is taken
25 out of the package?

1 A. The needle is sterile.

2 Q. And does touching the needle mean that it
3 is no longer sterile?

4 A. That's incorrect. Touching the needle
5 with your bare hands is the issue. If I recall
6 correctly, the executioner described putting on
7 gloves and then, if I remember right, swabbing the
8 tip of the needle with the alcohol swab, which is
9 not recommended.

10 Q. If a compounded preparation is drawn up
11 into a syringe in a non-sterile environment, how
12 soon must it be administered?

13 A. In the setting of diagnosis, care,
14 treatment, and healing it would be within one hour.

15 Q. And the caveat you gave to that answer is
16 in a diagnostic setting, clinical setting. Are you
17 suggesting that those standards don't apply in this
18 context?

19 A. Those are standards set forth by
20 recommendations by the USP and enforced by the FDA,
21 which means it has to be applicable in the setting I
22 just mentioned, which would be diagnosis, care,
23 treatment, and healing, or in some cases a patient's
24 home. This is none of the above.

25 Q. And so, in your opinion, because this is

1 neither a patient's home or a clinical setting,
2 those standards do not apply?

3 A. No, my opinion is, is that the
4 recommendation is within one hour. However, it's
5 important to remember why that is the
6 recommendation. And the risk is predominantly
7 sterility, which is not an issue here as the impact
8 of that is hours to days after drug administration.
9 But that's why -- I'm explaining that's why that's
10 my opinion.

11 Q. If a compounded preparation is not drawn
12 up -- excuse me, if a compounded preparation is
13 drawn up in a non-sterile environment and it's not
14 administered within one hour, does the risk of
15 precipitation increase?

16 A. Is that a general question, I'm sorry, or
17 specific to one of the LICs?

18 Q. I'm asking as a general pharmacological
19 principle about compounded preparations. Is the
20 concern about precipitation one of the reasons why
21 the USP requires a compounded preparation to be
22 administered within one hour if drawn up in a
23 non-sterile environment?

24 A. That's actually one -- that is actually
25 compounded or CSP specific, it's not applicable to

1 all. Because if your medication is in solution
2 already, it's irrelevant.

3 Q. What about a solution made from a
4 reconstituted powder; such as, vecuronium bromide?

5 A. Again, it'd be irrelevant, based on the
6 references I've already provided. Vecuronium is
7 stable with sterile water for 24 hours at room temp
8 and bacteriostatic water for five days. So whether
9 it's used within an hour or not is irrelevant. But
10 that's why.

11 Q. So under the USP, vecuronium bromide that
12 is reconstituted in a non-sterile environment does
13 not need to be administered within one hour?

14 A. That is a hundred percent correct, because
15 you have scientific literature and data that prove
16 otherwise.

17 Q. And that's what the USP requires?

18 A. Correct. Which goes a hundred percent
19 against what the manufacturer requires. So you
20 actually go to the manufacturer, because they're the
21 ones that made the drug.

22 Q. And under USP 797, if a drug is drawn up
23 in a syringe in a non-sterile environment and not
24 administered within one hour, is it considered
25 expired?

1 A. In the setting of diagnosis, care,
2 treatment, and healing, that is correct.

3 Q. And is that preparation then considered an
4 immediate use compounded sterile product?

5 A. These are immediate use preparations,
6 that's correct.

7 Q. Were you asked to give an opinion on what
8 portions of the USP should -- or do apply to the
9 execution context?

10 MR. SUTHERLAND: Object to the form.
11 You can answer.

12 THE WITNESS: Well, I think I've
13 already been opining. If we read the TDOC
14 manual, I thought it was page 35, it's pretty
15 clear, the USP is applicable to the pharmacist
16 and pharmacy preparing, testing, and sending
17 the LIC, it is not applicable to the person
18 diluting and administering it, as outlined,
19 because the TDOC is not regulated nor reviewed
20 by USP or the FDA, that I'm aware of.

21 BY MS. NELSON-MAJOR:

22 Q. Is reconstituting a powder drug into a
23 solution for injection considered compounding?

24 A. That's correct. It would be applicable in
25 the patient care setting, in a hospital, or a

1 patient's home.

2 Q. I want to turn your attention back to the
3 protocol, and I'm looking at page 34.

4 MR. SUTHERLAND: I'm sorry,

5 Ms. Nelson-Major, where are you?

6 Q. I'm looking at the protocol, introduced as
7 Exhibit 2, page 34.

8 A. Okay.

9 Q. You just testified that it was your
10 reading of the protocol that the USP standards that
11 the protocol references only apply to the
12 compounding pharmacy. And I want you to clarify for
13 me where in the protocol you see that limitation.

14 A. Sure. In the paragraph it says very
15 clearly, "Chemicals used in lethal injection
16 executions will either be FDA-approved commercially
17 manufactured drugs; or, compounded preparations
18 prepared in compliance with pharmaceutical standards
19 consistent with the United States Pharmacopeia and
20 accreditation Departments, and in accordance with
21 applicable licensing regulations."

22 Nowhere in that paragraph does it state
23 TDOC, nor is it a standard, is held to USP
24 regulatory requirements -- well, they're not
25 actually regulatory requirements, they're

1 recommendations, when diluting, administering,
2 preparing, storing the LIC. But it's continued on
3 page 35, if you want me to go to it.

4 Q. That is the only question I had about that
5 portion. I'm going to take down -- I'm not sharing
6 my screen anymore.

7 Are you aware that TDOC prepared the
8 syringes of vecuronium bromide and potassium
9 chloride two hours prior to administering the drugs
10 to both Donnie Johnson and Billy Ray Irick, the two
11 men executed under this protocol?

12 A. From my review of the records, that's
13 correct.

14 Q. And assuming USP 797 applies, the second
15 and third drugs TDOC used to execute Mr. Irick
16 and Mr. Johnson were expired under the USP; is that
17 correct?

18 A. Under that hypothetical --

19 MR. SUTHERLAND: Excuse me. Object to
20 the form. You can answer.

21 THE WITNESS: Sorry. Under that
22 hypothetical, that would be correct.

23 BY MS. NELSON-MAJOR:

24 Q. I'm going to return you back to your
25 report, on page 13. I'm looking at the second full

1 paragraph, which begins, "The inmate is prepared for
2 lethal injection by first obtaining intravenous (IV)
3 access." Do you see that?

4 A. I do. That's correct.

5 Q. And in this paragraph you summarize what
6 the protocol says about establishing IV access?

7 A. That's correct.

8 Q. Have you ever obtained IV access on a
9 patient?

10 A. Have I physically obtained IV access on a
11 patient? No.

12 Q. Is that something you were trained to do?

13 A. Trained to establish IV access? No.

14 Trained to evaluate it? Yes.

15 Q. And where did you receive IV training?

16 A. During residency and observation during
17 the last 20 years of my career directly with humans,
18 patients.

19 Q. Are you offering an opinion on the
20 procedures the execution team uses to establish IV
21 access?

22 MR. SUTHERLAND: Object to the form.

23 You can answer.

24 THE WITNESS: No, other than what I've
25 stated, which is it's an antecubital fossa,

1 which if you're familiar, it's the large vein
2 in the inner elbow which is utilized, an
3 18-gauge needle is what they utilize, which is
4 fairly large, and that minimizes any
5 irritation, whether it's from saline or any
6 other drug. Oh, sorry. Go ahead.

7 MS. NELSON-MAJOR: No, please finish
8 your answer.

9 THE WITNESS: Notably, it's placed by
10 EMTs. And so if you're familiar with EMTs in
11 the field, the field where they present to
12 somebody's home or to a gunshot wound victim,
13 is not a sterile area, they're placing these
14 there.

15 The reason I mention that is you keep
16 mentioning USP. Well, any medication EMTs are
17 drawing up in the field and administering are
18 not discarded in an hour, and that's clearly a
19 patient care setting. So that would mean every
20 EMS and EMT in the country is violating that
21 standard. So that's why I'm saying it doesn't
22 apply here.

23 BY MS. NELSON-MAJOR:

24 Q. And do EMTs routinely draw up medications
25 into syringes prior to administration and then wait

1 to administer them? Is that what you're saying?

2 A. Negative. You keep mentioning the
3 expiration time. And what I'm mentioning and
4 clearly stating, in real life or clinical practice,
5 drawing up and administering within an hour, even
6 for an EMT that's going en route, the drug is not
7 discarded. They're drawing it up because they need
8 it or might need to administer it. They don't throw
9 everything out after one hour and draw everything up
10 again.

11 So I'm stating there are clearly exceptions
12 even in a patient care setting where USP as a
13 recommendation says, yeah, draw it up into a syringe
14 and toss it out after 59.9 minutes, and what I'm
15 clearly stating is that's not true nor the reality.

16 Q. And in your clinical practice, how often
17 do you draw up medications more than an hour in
18 advance of them being administered to a patient?

19 A. We're preparing them for providers, so
20 they're already drawn up in a hood. But from my
21 observation, yes, things are drawn up in advance;
22 for example, in an organ transplant case, where they
23 may not necessarily be discarded exactly at the 61-
24 minute mark. That's all I'm stating.

25 Q. And you stated that when you draw them up

1 in a syringe, it's done in a hood; is that correct?

2 A. That's correct, unless it was an
3 emergency. For the setting of diagnosis, treatment,
4 care, and healing.

5 Q. And why in a non-emergency situation are
6 those drugs drawn up in a hood?

7 A. The main reason is actually sterility. So
8 there is a possibility of infection or in some case
9 a pyrogenic response, which is a fever, which could
10 be noted hours to days after administration. That
11 is the main reason.

12 Q. The next paragraph on your report on page
13 13 states, "Standards for point of care use by
14 patients are similar to those demonstrated and used
15 at an execution."

16 What standards are you referring to here?

17 A. It would be the ones outlined on USP, as I
18 stated on page 29. The responsibility after leaving
19 the pharmacy is upon the recipient, with the
20 instructions provided.

21 Q. Then you state, "The pharmacy provides
22 detailed instructions for drug storage, supplies
23 required for reconstitution, and reconstitution of
24 the medication prior to administration."

25 Have you seen the instructions that the

1 pharmacy provides to TDOC for reconstituting the
2 vecuronium bromide?

3 A. No. Those are followed in accordance with
4 the package insert that comes with every single
5 vial, because it's manufactured, not produced as a
6 CSP.

7 Q. Can you give an example of how a patient
8 may compound a sterile preparation within their own
9 home?

10 A. Sure. It would be exactly outlined as
11 described in the instructions from the pharmacy for
12 either midazolam or potassium chloride.
13 Instructions meaning, in general, how it should be
14 stored, how it should be reconstituted, and a
15 procedure for drawing out the medicine.

16 Q. Is it your opinion that the level of
17 instruction and precaution required to carry out an
18 execution need only be equivalent to the level of
19 instruction, precaution that a patient uses at home
20 when dealing with a CSP?

21 MR. SUTHERLAND: Objection to the form.
22 You can answer.

23 THE WITNESS: That's correct, for the
24 lay public. I believe the instructions
25 provided were detailed enough for a layperson

1 to follow.

2 BY MS. NELSON-MAJOR:

3 Q. I'm going to direct you to page four of
4 your report.

5 A. Okay.

6 Q. Do you see the section titled:
7 Consciousness check?

8 A. I do, yes.

9 Q. Are you offering an opinion on the
10 adequacy of the consciousness check in TDOC's
11 protocol?

12 A. I don't perform consciousness check. No.
13 But my main purpose of putting that in there is
14 outlining TDOC's protocol, which if you carefully
15 review it, actually mimics about a half a dozen of
16 the studies referenced in the different reports on
17 the Plaintiff side.

18 Q. So you're not offering an opinion on the
19 adequacy of the consciousness check?

20 A. No, just that it's the same as what they
21 used when they were studying midazolam in those
22 scenarios, it's almost verbatim.

23 Q. And in those studies that you're
24 referencing, what was the noxious stimuli or other
25 stimuli that was administered to those patients?

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1 A. Well, that's in the setting which you have
2 to clearly define is in research, which means first
3 we have to get patient consent, and it's in the
4 setting of diagnosis, treatment, care or healing.
5 And in that setting, the patients again consent to
6 the study, and the investigators did the exact same
7 protocol that's outlined almost verbatim there.

8 Q. And what level of sedation were those
9 studies assessing?

10 A. They were assessing therapeutic dosing of
11 midazolam.

12 Q. And in those studies were the patients
13 given a stimulus after administration of the
14 midazolam?

15 MR. SUTHERLAND: I'm going to object to
16 the form.

17 THE WITNESS: It would depend on the
18 study and how it was actually presented. Some
19 refer to actual surgery, if I recall
20 correctly, some refer to additions of either
21 an inhaled anesthetic gas, if I remember
22 right, and others had an intravenous opioid.

23 So, again, it's not the same thing we're
24 talking about because none of them utilized
25 500 milligrams of midazolam. But the

1 consciousness check was exactly the same, that
2 was my point, for a therapeutic dose.

3 BY MS. NELSON-MAJOR:

4 Q. And as part of your clinical duties, how
5 often do you personally assess a patient's
6 consciousness?

7 A. Oh, I already told you, I don't --

8 MR. SUTHERLAND: Object to the form.
9 Object to the form. You can answer.

10 THE WITNESS: Sorry about that. No, I
11 don't assess consciousness checks. I've
12 already stated that.

13 BY MS. NELSON-MAJOR:

14 Q. And what does consciousness mean?

15 A. My opinion and my --

16 MR. SUTHERLAND: Object to the form.
17 You can answer.

18 THE WITNESS: It would be awareness.

19 BY MS. NELSON-MAJOR:

20 Q. You said in your opinion. Where does that
21 definition come from?

22 A. Consciousness? That's my understanding as
23 a clinician working the last 20 years in a hospital.

24 Q. If a person is unconscious, can they feel
25 pain?

1 MR. SUTHERLAND: Object to the form.
2 You can answer.

3 THE WITNESS: They can feel pain.
4 However, the difference is, and the question
5 is, can they experience pain.

6 BY MS. NELSON-MAJOR:

7 Q. Well, my question was, if a person is
8 unconscious, can they feel pain?

9 MR. SUTHERLAND: Object to the form.
10 You can answer.

11 THE WITNESS: I don't recall if they
12 can feel pain. My experience and the way I
13 always understood it is if they can experience
14 pain.

15 BY MS. NELSON-MAJOR:

16 Q. If a person is unconscious, can they
17 respond to someone saying their name?

18 MR. SUTHERLAND: Object to the form.
19 You can answer.

20 THE WITNESS: According to the studies,
21 they did not respond to verbal stimuli.

22 BY MS. NELSON-MAJOR:

23 Q. I'm asking a more general question about
24 the parameters of consciousness, not the particular
25 midazolam studies you're referencing. But if a

1 person is unconscious, as a general matter, can they
2 respond to someone saying their name?

3 MR. SUTHERLAND: Object to the form.

4 You can answer.

5 THE WITNESS: Based on my
6 understanding, I don't believe so, no.

7 BY MS. NELSON-MAJOR:

8 Q. And you were distinguishing between
9 feeling pain and experiencing pain. If a person is
10 unconscious, can they experience pain?

11 MR. SUTHERLAND: Object to the form.

12 You can answer.

13 THE WITNESS: In the setting of
14 500 milligrams of intravenous midazolam, no.

15 BY MS. NELSON-MAJOR:

16 Q. I'm asking a general question about the
17 parameters of consciousness, unconscious versus
18 conscious. If a person is unconscious, can they
19 purposely respond to repeated or painful
20 stimulation?

21 MR. SUTHERLAND: Same objection.

22 THE WITNESS: I don't have an opinion.

23 BY MS. NELSON-MAJOR:

24 Q. And when you say you don't have an
25 opinion, is that because you don't know the answer

1 or because you just don't have an opinion? Like,
2 can you explain that?

3 MR. SUTHERLAND: Object to the form.

4 THE WITNESS: Go ahead.

5 MR. SUTHERLAND: Object to the form.

6 You can answer.

7 THE WITNESS: No, I just don't have an
8 opinion.

9 BY MS. NELSON-MAJOR:

10 Q. Have you not thought about that question
11 before?

12 A. No, I have not thought of that question.
13 That's why I don't have an opinion.

14 Q. Is an unconscious person raiseable to
15 painful stimulus?

16 MR. SUTHERLAND: Object to the form.

17 THE WITNESS: My understanding is, they
18 would not be, no.

19 BY MS. NELSON-MAJOR:

20 Q. And are you aware that the American
21 Society of Anesthesiologists have defined levels of
22 sedation on a continuum?

23 A. I'm aware of that in the setting of
24 surgery, yes, that's correct.

25 Q. And you earlier stated that you don't have

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1 an opinion of whether -- if a person is unconscious,
2 can they purposely respond to repeated or painful
3 stimulus. Do you have an opinion in terms of the
4 midazolam dose in this case, whether that would be
5 sufficient?

6 MR. SUTHERLAND: Object to the form.

7 THE WITNESS: A 500-milligram
8 intravenous dose of midazolam given
9 250 milligrams at a time, after waiting two
10 minutes, yeah, I would believe the patient
11 would be unconscious, it's my opinion.

12 BY MS. NELSON-MAJOR:

13 Q. All right. I'm going to pull up the
14 American Society of Anesthesiologists chart that we
15 were just talking about.

16 MR. SUTHERLAND: I just received it.

17 And, Dr. Patel, it is on its way.

18 A. Okay.

19 Q. You testified that you're aware that the
20 ASA has offered definitions of sedation, levels of
21 sedation in the surgery context. Have you seen this
22 chart before?

23 A. No, I have not. I'm aware the ASA has
24 levels. But I'm not an anesthesiologist. I don't
25 know the chart.

1 Q. Do you see at the top of the chart that
2 there's four categories listed, beginning with,
3 "Minimal Sedation Anxiolysis"?

4 A. I see that, yes.

5 Q. And then it progresses to "Moderate
6 Sedation/Analgesia"?

7 A. I see that, yes.

8 Q. Then it progresses to "Deep
9 Sedation/Analgesia"?

10 A. That's correct.

11 Q. And then the last category is "General
12 Anesthesia."

13 A. Yes, I see that.

14 Q. And there's a corresponding level of
15 responsiveness for each of those categories.

16 A. Okay.

17 Q. So what level of sedation on this chart
18 corresponds to your definition of unconsciousness?

19 MR. SUTHERLAND: Object to the form.

20 THE WITNESS: Well, I never said any
21 of them correlate to this chart, because
22 I'm not an anesthesiologist. So I don't use
23 this chart.

24 BY MS. NELSON-MAJOR:

25 Q. When you were employed by Rush Medical

1 Center, were you a professor?

2 A. I was -- that's correct. It's an
3 associate professor.

4 Q. And what departments were you an associate
5 professor in?

6 A. Within pulmonary critical care and
7 anesthesiology.

8 Q. And in your duties as an associate
9 professor in anesthesiology, did you ever consult
10 this chart?

11 A. No. I taught about medications.

12 Q. So elsewhere in your report -- on page
13 one, if you'd like to pull that up.

14 A. Sure.

15 Q. I'm looking at the last paragraph in the
16 Introduction section. And you write that the inmate
17 will be insensate during the transition to death.
18 Do you see that?

19 A. That's correct.

20 Q. Is unconscious the same thing as being
21 insensate?

22 MR. SUTHERLAND: Object to the form.

23 THE WITNESS: My understanding of
24 insensate is, unconscious and unable to
25 respond to physical stimuli.

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1 BY MS. NELSON-MAJOR:

2 Q. And then on page five of your report --
3 I'm turning to the -- page five. There's a section
4 entitled: Contingency provision.

5 A. Okay.

6 Q. And in here -- in this paragraph you write
7 if the inmate is still conscious following the
8 consciousness check, two additional syringes of
9 midazolam 250 milligrams per syringe are already
10 prepared and ready to be administered to the inmate.

11 Is it your belief that all of the midazolam
12 syringes are prepared prior to the execution
13 commencing?

14 MR. SUTHERLAND: Ms. Nelson-Major, I'm
15 sorry, where are you referring to, where are
16 you?

17 MS. NELSON-MAJOR: There's a paragraph
18 with a heading titled "Contingency provision"
19 on page five.

20 MR. SUTHERLAND: Okay.

21 BY MS. NELSON-MAJOR:

22 Q. And my question, Dr. Patel, is: Is it
23 your belief that all of the midazolam syringes are
24 prepared prior to the execution commencing?

25 A. My understanding is, the syringes, again

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1 tagged red and blue, are prepared prior.
2 Contingency, if I recall correctly, were the blue
3 ones, which would be inclusive of this midazolam.
4 That was my understanding from reading the protocol.
5 Or manual, rather.

6 Q. And you write that following
7 administration of the two additional syringes, the
8 warden conducts another consciousness check before
9 proceeding with the second and third drugs.

10 Does the protocol say what happens if the
11 inmate responds to the consciousness check after
12 administration of the second or backup set of
13 midazolam syringes?

14 A. I don't recall, no.

15 Q. Moving on to the section below entitled:
16 Drugs & Their Effects. What class of drugs does
17 midazolam fall within?

18 A. The class -- you mean the drug class
19 itself? It's benzodiazepines.

20 Q. And in your report you describe midazolam
21 as a sedative-hypnotic. What does sedative-
22 hypnotic mean?

23 A. As it states, the drug is sedating and/or
24 can transition to hypnosis depending on, again, the
25 benzodiazepine administered, the dose administered,

1 and the route administered.

2 Q. And what does hypnosis mean in a
3 pharmacologic sense?

4 A. In my understanding and defining this for
5 lay public and for students is, they are unaware of
6 their surroundings.

7 Q. Are all benzodiazepines sedative-
8 hypnotics?

9 A. They are in a class known as sedative-
10 hypnotics, all of them, from my understanding, yes.
11 But the reason is, is because sedative and hypnotic,
12 you have to understand, is a transition. Something
13 can be sedative and not hypnotic, but it's a
14 progression forward.

15 Q. And are there other types of drugs besides
16 benzodiazepines that are sedative-hypnotics?

17 A. Depending on the medication, the dose, and
18 the route of administration, yes, there can be other
19 classes. The only other one I'm aware of that can
20 be classified as such are particular barbiturates.

21 Q. And later in that paragraph you write that
22 the drug class of sedative-hypnotics is "designed to
23 suppress the central nervous system (brain),
24 resulting in a significant depressed level of
25 consciousness and awareness."

1 What is the significance --

2 MR. SUTHERLAND: I'm sorry,

3 Ms. Nelson-Major, where are you?

4 MS. NELSON-MAJOR: The same paragraph,
5 the next sentence.

6 MR. SUTHERLAND: What paragraph? On
7 what page?

8 MS. NELSON-MAJOR: We're still on page
9 five, "Drugs & Their Effects," still under
10 midazolam, the second sentence under the
11 subheading "Midazolam."

12 MR. SUTHERLAND: Thank you.

13 BY MS. NELSON-MAJOR:

14 Q. So my question is, what do you mean by
15 "significant depressed level of consciousness and
16 awareness"?

17 A. As it states, midazolam is a fairly
18 fast-acting benzodiazepine based on its properties,
19 and so it does cause significant depressed levels of
20 consciousness and awareness, which is why it's
21 utilized as a pre-anesthetic medication or an
22 induction anesthesia.

23 Q. Is that true regardless of the dose at
24 which it is administered?

25 A. That's not a hundred percent correct. So

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1 in a therapeutic setting, again, in the setting of
2 diagnosis, care, treatment, and healing, it would be
3 either one milligram, two milligrams, or five
4 milligrams. In a pre-induction dose, for example in
5 rapid sequence intubation, it could be upwards of
6 0.4 to 0.6 milligram per kilogram. So the
7 escalation of the dose correlates with the depressed
8 level of consciousness and awareness.

9 Q. And starting on the bottom of page five
10 into page six, you discuss midazolam's mechanism
11 of action. What does that term, "mechanism of
12 action," mean?

13 A. How I would describe it to students or the
14 lay public is, it's how in essence the drug works or
15 its effects on the brain.

16 Q. And what is midazolam's mechanism of
17 action?

18 A. Its mechanism of action falls into a
19 series of steps. Meaning, if you go to that figure
20 which is below, it first binds to the gamma-
21 aminobutyric, or GABA, G-A-B-A, receptor. After the
22 drug of the benzodiazepine class but specifically
23 midazolam binds, it causes GABA to bind to the
24 receptor itself, causing then an influx of what
25 you'll see there, that chloride ion.

1 After -- and as it moves through that
2 channel it causes a hyper-excitation which then
3 nullifies any signal transmission, in this case
4 awareness and consciousness, which is a layman's
5 term for neuronal transmission in the brain.

6 Q. Can midazolam exert an effect on the GABA
7 receptor if GABA is not present?

8 A. My understanding is, midazolam and
9 benzodiazepines require gamma-aminobutyric acid, the
10 most abundant amino acid in the brain.

11 Q. So at the bottom of the page, below that
12 diagram you just referenced, you write, "Once the
13 GABA binds to the GABA receptor the result is
14 inhibition of brain neuronal activity; otherwise
15 described as a loss of consciousness and awareness."

16 Are you saying that once any amount of GABA
17 binds to a GABA receptor a person will lose
18 consciousness?

19 A. At a therapeutic dose, that occurs. At a
20 dose that we're discussing of 500 milligrams
21 intravenously given 250 milligrams apart will
22 certainly do that. Yes, that's what I'm saying.

23 Q. I'm asking as a general principle of
24 midazolam's mechanism of action.

25 MR. SUTHERLAND: Object to the form.

1 THE WITNESS: That's correct, the
2 therapeutic dose would cause that.

3 BY MS. NELSON-MAJOR:

4 Q. What does "ceiling effect" mean in
5 pharmacological terms?

6 A. Ceiling effect is kind of a layman's way
7 of understanding. And why they calling it ceiling;
8 for example, the ceiling in your home is when you go
9 past a certain -- you can't go past a certain
10 threshold to not get clinical effect.

11 Q. So greater doses do not produce greater
12 pharmacological effects above a maximum dose? Is
13 that a fair way of putting it?

14 A. Generally, it's discussed and understood
15 as a plateau, that's correct.

16 Q. In your opinion, does midazolam have a
17 ceiling effect?

18 A. My opinion is, medications and drugs used
19 in specifically the central nervous system do have a
20 ceiling effect. However, I'm not aware of what the
21 ceiling dose is for midazolam.

22 Q. So you're not aware of the dose; but, in
23 your opinion, the ceiling does exist for midazolam?

24 A. The concept and the principle exist,
25 that's correct. I'm not aware of what dose that

1 occurs at, no.

2 Q. And does a ceiling effect for midazolam
3 exist because the body supply of GABA is limited?

4 A. It's not necessarily that the supply of
5 GABA is limited. It's based on its mechanism of
6 action where it is dependent on GABA and the
7 binding. However, other medications that work in
8 the central nervous system, or brain, have other
9 mechanisms to cause unconsciousness that midazolam
10 does not possess.

11 Q. And what are those other drugs that you're
12 referencing there?

13 A. The drugs that have other ways of
14 activating the GABA receptor; for example, could be
15 the barbiturates is one example.

16 Q. And do barbiturates have a different
17 mechanism of action than benzodiazepines?

18 A. They are very similar, with only one
19 distinction.

20 Q. And what's that distinction?

21 A. They can cause the hyperpolarization with
22 the presence of GABA and without the presence of
23 GABA, as described on the diagram above.

24 Q. And do barbiturates also block exi-- I can
25 never say this word, so I apologize. Do they also

1 block the excitation, excuse me, of neurons at
2 glutamate receptors?

3 A. That's correct. That can be one of their
4 mechanisms, in addition to other anesthetics.

5 Q. Does midazolam block excitation of neurons
6 at glutamate receptors?

7 A. Not that I'm aware of, no.

8 Q. And you just mentioned that figure on page
9 six. Why are the barbiturates depicted at a
10 different place on the GABA receptor than the
11 benzodiazepines?

12 A. I guess I don't understand the question.
13 Why are they there instead of exactly where the
14 benzodiazepines are?

15 Q. Is there significance to the fact that the
16 barbiturates are depicted lower down on the GABA
17 receptor than the benzodiazepines?

18 A. That is their associated binding spot and
19 which is dual and can cause the chloride flux for
20 hyperpolarization, as I describe. They're just
21 different binding sites on the same receptor.

22 Q. And to be clear, barbiturates can work
23 independently of GABA; is that correct?

24 A. That's a correct statement.

25 Q. And does that mean that barbiturates can

1 produce greater levels of central nervous system
2 depression than benzodiazepines?

3 A. Depending on the dose and the route of
4 administration and the particular barbiturate,
5 that's correct.

6 Q. Scrolling down to page 15 of your report.
7 And I'm looking at the first full sentence at the
8 top of page 15 where you write, "Midazolam has been
9 demonstrated to effect experiences of pain in a
10 dose-dependent fashion." And then you have an
11 endnote citation, number 29.

12 And at endnote 29 you cite an article
13 entitled: "Neuropsychopharmacological effects of
14 midazolam on the human brain," by Wang, et al.; is
15 that right?

16 A. That's correct.

17 Q. I want to ask you a couple of questions
18 about the article.

19 A. Sure. Could you just -- would you be able
20 to send it real quick? That's all.

21 Q. Yes, I can do that.

22 A. Thank you.

23 MR. SUTHERLAND: Still waiting on it.
24 I'm still waiting.

25 MS. LEONARD: I sent it about three

1 minutes ago. I'm not sure what the delay is,
2 unfortunately. But, hopefully, it's going to
3 get through to you soon.

4 BY MS. NELSON-MAJOR:

5 Q. Dr. Patel, I have a couple more general
6 questions about this article. We could see if we
7 could answer those, and then hopefully the document
8 will come in. But if you feel like you can't answer
9 any of those questions without seeing a copy of the
10 article, we can pause and wait for it to arrive.
11 Does that sound okay?

12 A. Yeah, that's fine.

13 MS. LEONARD: I can also try to send
14 another copy again in the meantime. I'm not
15 sure what's going on. But might as well give
16 it a shot.

17 MR. SUTHERLAND: Sure.

18 BY MS. NELSON-MAJOR:

19 Q. So we were talking about the article by
20 Wang, et al., that you cite for the proposition
21 that, "Midazolam has been demonstrated to effect
22 experiences of pain in a dose-dependent fashion."

23 In the Wang article the authors discuss a
24 number of studies on the impact that midazolam had
25 on different aspects of brain functioning; is that

1 right?

2 A. In the general context, that's correct.

3 Q. And one study the authors looked at
4 specifically was about the impact midazolam has on
5 brain activity related to pain. Is that the study
6 on which you're basing your opinion that, "Midazolam
7 has been demonstrated to effect experiences of pain
8 in a dose-dependent fashion"?

9 MR. SUTHERLAND: Yeah, Ms. Nelson-
10 Major, I would -- I'm going to request that
11 he -- if you're going to refer to specific
12 areas, I'd like you to be able to show it to
13 him, so he can review it, so we're not talking
14 in generalities. I think those are specific
15 questions. I still haven't received it yet.

16 MS. NELSON-MAJOR: Mr. Sutherland, this
17 is an article you provided to us. I don't
18 know if you have access on your own system to
19 those documents, but that's another option if
20 it continues to not go through to you.

21 MS. LEONARD: Or should I -- could I
22 send it to Rob Mitchell or Dean? Or is there
23 someone else I could maybe try to send it to
24 you? I'm open to suggestions.

25 MR. SUTHERLAND: Yeah, you can try to

1 send it to Rob and Dean. I don't know why it
2 would make a difference, but you're certainly
3 welcome to try.

4 MS. LEONARD: Okay, I'll try that now.

5 MR. SUTHERLAND: Yeah. I just got both
6 of them at the same time. All right. And a
7 third. On its way.

8 THE WITNESS: Okay.

9 BY MS. NELSON-MAJOR:

10 Q. Is this the Wang article that you cite in
11 your report?

12 A. That's correct.

13 Q. I'm going to mark this as Exhibit 12 --
14 13. Sorry about that. And we just agreed that this
15 article surveyed a number of studies about the
16 impact midazolam has on different parts of brain
17 functioning, correct?

18 A. That's correct. That was the premise for
19 them doing the study.

20 Q. And you specifically rely on this article
21 for discussion of the impact that midazolam has on
22 the human brain related to pain; is that correct?

23 A. That's correct.

24 Q. And, in particular, the Wang authors
25 discuss a study on page five of this article. I'm

1 looking at the bottom of page five, and there's a
2 citation in their discussion of the studies of
3 midazolam and pain.

4 A. Which citation numbers are you talking
5 about?

6 Q. I'm looking at citation 61.

7 A. Okay.

8 Q. Which is an article by Wise, et al.
9 entitled: "The anxiolytic effects of midazolam
10 during anticipation to pain revealed using fMRI."

11 Was this the study that you relied upon
12 when you said, "Midazolam has been demonstrated to
13 effect experiences of pain in a dose-dependent
14 fashion"?

15 A. These research and review that was
16 performed by Wang and their group is why I'm relying
17 on that, in addition to that study. But the last
18 sentence of that paragraph is actually where it
19 talks about dose-dependent manner.

20 Q. And looking at that study referenced in
21 that paragraph that I just mentioned by Wise,
22 et al., did you read that particular study?

23 A. Did I pull the Wise study? No, I did not
24 pull the Wise paper. I pulled and researched and
25 found this research paper, which is why I referenced

1 it.

2 Q. And I understand that you didn't read the
3 Wise study. But what does the word "anxiolytic" in
4 the title of that study mean?

5 A. Anxiolytic from -- as just a general
6 definition, means anxiety. But I don't know how
7 they actually used it in that particular study,
8 because there are varied definitions.

9 Q. What is anticipation to pain?

10 A. I guess I don't follow.

11 MR. SUTHERLAND: Object to the form.

12 THE WITNESS: Yeah.

13 BY MS. NELSON-MAJOR:

14 Q. Are you aware of the concept anticipation
15 to pain?

16 A. I am aware of that, yes.

17 Q. And what does that concept refer to?

18 A. It's actually most often used in the
19 setting of surgery, so in the -- again, the setting
20 of care, treatment, diagnosis, and healing, where
21 the patient is anticipating pain before a procedure
22 or surgery.

23 Q. So it's distinct from the experience of
24 pain itself.

25 A. It's part of the experience overall,

1 because you're anticipating what's coming toward
2 you.

3 Q. Anticipation of the pain that might occur
4 is different, though, than the actual experience of
5 the pain that does in fact occur. Would you agree
6 with that?

7 A. I have reviewed and understand it as an
8 umbrella term, it is one of the same.

9 Q. Are you aware that the Wise study found
10 that midazolam had no significant effect on brain
11 activity associated with experience of pain, as
12 opposed to the anticipation to pain?

13 MR. SUTHERLAND: Object to the form
14 based on his prior answer.

15 THE WITNESS: No, because I have not
16 reviewed the Wise study, so I can't comment.

17 BY MS. NELSON-MAJOR:

18 Q. When you say that, "Midazolam has been
19 demonstrated to effect experiences of pain," is that
20 the same thing as saying that midazolam has an
21 analgesic effect?

22 MR. SUTHERLAND: Object to the form.

23 THE WITNESS: If analgesia, and part
24 of it is experiencing and anticipation of pain
25 then, yes.

1 BY MS. NELSON-MAJOR:

2 Q. And what does analgesia mean?

3 A. Analgesia, from my understanding and
4 background and experience, is the treatment of pain.

5 Q. So, in your opinion, midazolam has an
6 analgesic effect?

7 A. No, that's not what I said at all.

8 Q. So explain to me why that's an incorrect
9 statement.

10 A. Why midazolam has an analgesic effect?

11 Q. Well, you said, "That's not what I said at
12 all." Then can you explain to me what you did say?
13 Because I think I misheard you.

14 A. Correct. Based on the dosage, the route
15 of administration of two doses of 250 milligrams of
16 intravenous midazolam, the person will be rendered
17 unconscious, insensate, so will not experience any
18 pain. I never said midazolam was an analgesic.

19 Q. At a clinical dose does midazolam affect
20 the experience of pain?

21 A. How would you define clinical dose?

22 Q. I would defer to your definition of what a
23 clinical dose is.

24 MR. SUTHERLAND: Object to the form.

25 THE WITNESS: Between one and five

1 milligrams? No. IV.

2 BY MS. NELSON-MAJOR:

3 Q. And at what dose does midazolam start to
4 have an effect on the experience of pain, in your
5 opinion?

6 A. At doses administered for anesthesia
7 induction and/or in the setting of rapid sequence
8 intubation, which is used therapeutically pretty
9 commonly.

10 Q. So just to be clear, in your opinion,
11 midazolam does not have an analgesic effect, but it
12 does experience -- does affect experiences of pain;
13 is that right?

14 A. That's correct, likely related to it
15 rendering the person unconscious and unaware and
16 unresponsive to physical stimuli, or insensate.

17 Q. So in your report you list three clinical
18 uses of midazolam --

19 A. One sec. Sorry, let me just pull up the
20 report.

21 Q. Page seven.

22 A. And you said page seven?

23 Q. Uh-huh. Yes. And then subheading number
24 four.

25 A. Sure.

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1 Q. You list three clinical uses in this
2 section, you say that it's used as a procedural
3 anesthetic, as an induction agent in anesthesia, and
4 third, in the Intensive Care Unit while patients are
5 on a mechanical ventilator or life support.

6 Are those the three uses of midazolam that
7 you're aware of?

8 A. No. That's why the sentence doesn't say,
9 "only."

10 Q. What other uses of midazolam are you aware
11 of?

12 A. Many. It could be used for patients not
13 on the mechanical ventilator that need comfort when
14 having difficulty breathing, it can be used for
15 acute agitation, that's not listed on there, it
16 could be used for refractory status, that's given as
17 intramuscular, it can be given as an infusion for
18 refractory status epilepticus, which is, again,
19 repetitive seizures that aren't broken with normal
20 therapies. Those would be probably the predominant
21 ones.

22 Q. And what's refractory status?

23 A. Seizures that are continuing to occur
24 despite therapy or treatment.

25 Q. Then you write in the next sentence, "In

1 regards to the procedures, low dose midazolam is
2 commonly utilized for procedures such as cardiac
3 catheterization and endoscopy."

4 What do you mean by the term "low dose"?

5 A. From my understanding and background,
6 training, experience is, that would be anywhere from
7 0.5 milligrams to 5 milligrams either given, and
8 generally given, in sequential amounts. So the
9 total could be 5, but it may not be, and generally
10 is not, five milligrams all at with once for adult
11 patients.

12 Q. Is midazolam used by itself during cardiac
13 catheterization procedures?

14 A. From what I've observed, yes, it can be.

15 Q. Is it often accompanied by an opioid?

16 A. It depends if the patient's saying they're
17 having pain. But oftentimes it's not. Which is the
18 catheter going through their femoral artery and then
19 with a camera viewing, after shooting the dye, the
20 structural relative patency of their coronary
21 arteries.

22 Q. And you said an opioid can be given if a
23 patient says they're in pain. Does that mean that
24 the patient is awake during the procedure?

25 A. That's correct. That's why it's called

1 conscious sedation, not unconscious sedation.

2 Q. So midazolam is used to achieve conscious
3 sedation during a cardiac catheterization?

4 A. That's my understanding of why it's used,
5 that's correct. And as an anxiolytic.

6 Q. Is midazolam used by itself during
7 endoscopy?

8 A. It can be, that's correct.

9 Q. Is it sometimes given with other drugs?

10 A. Depends. If they're actually doing a
11 colonoscopy and an endoscopy, which is maybe not as
12 preferred for the patient then, yeah, they might mix
13 it with an opioid, because they're going to be there
14 for a little bit longer period of time.

15 Q. And why in that circumstance would an
16 opioid be added?

17 A. I guess in layman terms, they're sticking
18 a scope up their bottom and they're putting a scope
19 down their throat and they're going to be there for
20 a couple hours. So generally they will provide a
21 small amount of an analgesic for comfort while the
22 patient's awake the entire time.

23 Q. Then you write, "However, when an
24 increased level of the depth of sedation and level
25 of consciousness are needed then escalating doses

1 are required."

2 Are you referring to needing an increased
3 level of sedation during an endoscopy or a cardiac
4 catheterization here?

5 A. No. That's why it's separated, because it
6 says when you need an increased level of depth of
7 sedation. And what we just discussed -- oh, sorry,
8 I wasn't done.

9 Q. I'm sorry. No, please finish your answer.
10 I thought you were done.

11 A. The scenarios described above are
12 conscious sedation. The ones described below, in my
13 opinion, are considered more depth of sedation,
14 which is not conscious sedation, it's deep.

15 Q. When you say the procedures discussed
16 below, are you referring to rapid sequence
17 intubation?

18 A. That would be a moderate to deep sedation,
19 in my opinion, type of procedure, yes. Or deep
20 sedation for a patient on the mechanical ventilator,
21 if that's what's required.

22 Q. When a patient is placed under deep
23 sedation for a mechanical ventilator, is midazolam
24 given by itself in that context?

25 A. Depending on -- oh, sorry, go ahead.

1 MR. SUTHERLAND: Object to the form.
2 You can answer.

3 THE WITNESS: The answer is, it
4 depends, it depends on your scenario and it
5 depends on the patient. Oftentimes it's
6 combined with an opioid to achieve deep
7 sedation in the context of the mechanical
8 ventilator, a depressed RASS score, in the
9 context of treatment and healing.

10 BY MS. NELSON-MAJOR:

11 Q. And why in the context of a mechanical
12 ventilator is an opioid often given?

13 A. The opioid is pared because it acts on the
14 mu receptor, which is the pain receptor.

15 Q. Does midazolam act on that receptor?

16 A. Midazolam does not act on the opioid
17 receptor, no, nor do barbiturates.

18 Q. And you refer to that receptor as the pain
19 receptor?

20 A. Mu receptors, mu 1 and 2, or m and u, are
21 considered the pain receptors. There's a mu 3, but
22 I don't think it's as clearly defined.

23 MR. SUTHERLAND: Ms. Nelson-Major,
24 we've been going about an hour and a half. Do
25 you mind if we take about a -- I don't know,

1 maybe a ten-minute break, restroom break?

2 MS. NELSON-MAJOR: That's fine.

3 VIDEOGRAPHER: Going off the record,
4 the time is 1:01.

5 (A brief recess was taken.)

6 VIDEOGRAPHER: Back on the record, the
7 time is 1:10.

8 BY MS. NELSON-MAJOR:

9 Q. Dr. Patel, I want to ask you a couple of
10 questions about rapid sequence induction. First the
11 basic one, what is rapid sequence induction?

12 A. Rapid sequence induction is, from my
13 understanding and experience has been, more related
14 to what I understand as RSI, which is rapid sequence
15 intubation, where a patient needs a tube in the
16 airway. And that plastic tube is placed by a
17 trained professional, generally an anesthesiologist
18 or a resident or a CRNA, or even EMTs.

19 Prior to that placement of that tube and
20 procedure, the first drug actually is midazolam, and
21 it could be in a range from anywhere from 0.4 up
22 towards 0.6 milligram per kilogram if even used
23 prior to surgery.

24 Q. And I meant to say intubation. So thank
25 you for correcting me.

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1 A. No problem.

2 Q. And it's often referred to as RSI for
3 short; is that right?

4 A. That's correct.

5 Q. And under what circumstances is RSI
6 performed?

7 A. The circumstance, it's generally -- the
8 two I'm aware of, it's either emergent, so the
9 patient's having very difficult time breathing,
10 either ventilating or oxygenating; so either the
11 mechanics of moving the air in and out or exchanging
12 oxygen and carbon dioxide. So that can be either
13 very quick or urgent, where it's seconds to minutes
14 are needed. Or, it could be a controlled setting
15 where they have the tube placed and the support
16 during a surgery, whether it's elective or not.

17 Q. And in the emergent context you mentioned,
18 the patient is usual unstable; is that right?

19 A. That's correct. That clinical context,
20 the patient could be unstable, they could have
21 abnormal blood pressure or heart rate or both. And
22 there could be a number of other things going on.
23 But it depends on the scenario.

24 Q. Potentially, that patient is non-fasted?

25 A. Non-fasted meaning they haven't been fa--

1 is what you mean they've eaten in the morning or
2 that day?

3 Q. In general, before a non-emergent surgical
4 procedure patients are instructed to fast; is that
5 correct?

6 A. Well, that's actually changed over the
7 years. So more recently, from what I'm familiar
8 with, some of the surgeries just require no food two
9 to four hours before, some even require liquids that
10 are acceptable two to four hours before. So that's
11 actually changed from what it was 10 or 20 years
12 ago, from my understanding.

13 Q. And why is it rapid, in a rapid sequence
14 induction?

15 A. My understanding is, because the effect of
16 the drug is within seconds. So, generally, it's
17 like a 30-to-60-second time window before the
18 placement of the plastic tube in their throat.

19 Q. And when a patient is being intubated for
20 a non-emergency surgery, is intubation done
21 differently than an RSI procedure?

22 MR. SUTHERLAND: Object to the form.
23 You can answer.

24 THE WITNESS: I'm not aware or have an
25 opinion that they're different. My

1 observation is, the medicines and what's being
2 used is virtually the same.

3 BY MS. NELSON-MAJOR:

4 Q. In your report you say that midazolam is
5 used as a "sole agent" during RSI. What do you mean
6 by "sole agent"?

7 A. Sure. Let me just get to it. Which page
8 were you referencing?

9 Q. I'm looking for the exact --

10 A. Just so I can get the context correct.

11 Q. The bottom of page seven onto the top of
12 page eight, the sentence carries over.

13 A. That is correct, it is the first drug
14 administered.

15 Q. And what other drugs are administered?

16 A. After the benzodiazepine, it's a
17 paralytic, like vecuronium or succinylcholine or
18 rocuronium.

19 Q. Is a pre-treatment drug often given prior
20 to beginning RSI?

21 A. It depends on the setting and availability
22 of the medicine.

23 Q. If a pre-treatment drug is available, is
24 it generally given before beginning RSI?

25 A. That's correct, it can be given prior.

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1 Q. My question is, if it is available, is it
2 usually given?

3 A. Correct, if the providers have access to
4 it and can administer it in a timely fashion, they
5 would.

6 Q. And what type of drugs are used as
7 pre-treatment?

8 A. It would be a low dose of fentanyl, it
9 could be a low dose of ketamine. Those would be two
10 examples.

11 Q. And what kind of drug is fentanyl?

12 A. Fentanyl is an opioid.

13 Q. And what about ketamine?

14 A. It's a phencyclidine, classified under the
15 anesthetics.

16 Q. And why are those types of pre-treatment
17 drugs given when they're available?

18 A. They augment the activity of the
19 benzodiazepine.

20 Q. And after the endotracheal tube is placed,
21 are other drugs given?

22 A. I guess I don't quite understand. Other
23 drugs for -- for what?

24 Q. Let me clarify. Are analgesics or
25 additional sedation drugs generally given after an

1 endotracheal tube is placed during an RSI procedure?

2 A. After the placement, that's correct.

3 Q. And what sorts of additional sedation
4 drugs or analgesics are generally given after
5 placement of an RSI tube?

6 A. Sure. About 30 to 45 minutes after the
7 procedure you'll have initial wearing off of the
8 induction agent, and in that instance an opioid is
9 usually administered, in that scenario and in that
10 context.

11 Q. And then on to page eight. I'm looking
12 for the exact sentence to point you to. The last
13 sentence in that paragraph you write, "The role of
14 midazolam administration for this procedure is to
15 provide relaxation of the airway muscles while
16 inducing an amnestic effect." Do you see that
17 sentence?

18 A. That's correct.

19 Q. What does amnestic mean?

20 A. From my understanding and from what I have
21 learned over the years, it creates a state of
22 amnesia.

23 Q. And what is a state of amnesia?

24 A. Not being able to remember the procedure
25 or recall it.

1 Q. So amnesia is different than analgesia; is
2 that correct?

3 A. That's correct. That's why it doesn't say
4 analgesic.

5 Q. So the role of midazolam in an RSI
6 procedure is to relax the airway muscles and induce
7 an amnestic effect. Am I paraphrasing that
8 correctly?

9 A. That's correct, before the placement of
10 the plastic tube in their throat, which is painful,
11 causes coughing and gagging, they're administered a
12 drug for anxiolysis and an amnestic effect. That's
13 a hundred percent correct.

14 Q. And anxiolysis means reduction in anxiety,
15 correct?

16 A. That is correct. That's one of the
17 purposes, besides sedation.

18 Q. So the midazolam given in an RSI procedure
19 isn't intended to induce an analgesic effect,
20 correct?

21 A. That's correct.

22 MR. SUTHERLAND: Object to form.

23 THE WITNESS: I'm sorry, go ahead.

24 MR. SUTHERLAND: Object to the form.

25 You can answer.

1 THE WITNESS: It's intended, as I
2 stated, before the placement of the plastic
3 tube and the coughing and gagging, to produce
4 a state of unconsciousness, relaxation, and
5 sedation.

6 BY MS. NELSON-MAJOR:

7 Q. In your clinical practice at the
8 University of Chicago Medicine, do you typically see
9 ketamine, etomidate, or midazolam being used as the
10 first drug in an RSI procedure?

11 A. Well, I don't administer the drugs, so I
12 don't have an opinion. My experience from
13 dispensing the medicines is, it could be any one of
14 the three.

15 Q. I'm going to pull up the product labeling
16 for midazolam that you cite in your report. And
17 I'll give you a minute for that to arrive to
18 Mr. Sutherland.

19 MS. LEONARD: Sorry, the delay was my
20 fault this time. I just sent it to you.

21 MR. SUTHERLAND: No, that's all right.

22 MS. LEONARD: Just making sure I had
23 the right thing.

24 MR. SUTHERLAND: That's okay. Here it
25 is. I just sent it to you, Dr. Patel.

1 THE WITNESS: Yep. Got it.

2 BY MS. NELSON-MAJOR:

3 Q. Is this the midazolam product labeling
4 that you cite in your report?

5 A. That's correct, this is the one approved
6 and reviewed by the Food and Drug Administration for
7 manufacturers, in this case it's Akorn.

8 Q. I'm going to mark this as Exhibit 14.
9 Could you please turn to page 17.

10 A. Sure.

11 Q. So at the bottom of the page you'll see it
12 says, "USUAL ADULT DOSE" in bold and capital
13 letters?

14 MR. SUTHERLAND: I'm going to be dense
15 here, but I'm not seeing pages.

16 THE WITNESS: Yeah, I'm not seeing that
17 either.

18 MS. NELSON-MAJOR: I'm wondering if we
19 are looking at different product labeling.

20 MR. SUTHERLAND: This says, "Midazolam,
21 Akorn, Inc." But it doesn't have page numbers
22 on it.

23 MS. NELSON-MAJOR: Oh, I'm looking at
24 the pdf page numbers, if that -- no?

25 MR. SUTHERLAND: Oh, they're just --

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1 oh, I see what you're saying.

2 MS. NELSON-MAJOR: They're not marked
3 on the page, the numbers.

4 MR. SUTHERLAND: Got you.

5 THE WITNESS: And it's page 17?

6 MS. NELSON-MAJOR: Correct. At the
7 very, very bottom it should say, "USUAL ADULT
8 DOSE."

9 THE WITNESS: I see that. Yes. Sorry,
10 I was looking for the page number.

11 BY MS. NELSON-MAJOR:

12 Q. It's a little bit confusing. My
13 apologies.

14 Does this portion of the product labeling
15 lay out the approved uses of midazolam?

16 A. The approved uses? No, I believe these
17 are the approved or at least recommended as reviewed
18 by the Food and Drug Administration, again, in the
19 setting of care, treatment, diagnosis, and healing.
20 That's correct.

21 Q. And the first portion is about
22 intramuscular administration. Do you see that?

23 A. I see that, yes.

24 Q. I'm scrolling down to the next page, 18,
25 where intravenous uses are discussed. Let me know

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1 when you see that.

2 A. I see that, yes.

3 Q. And under the word "INTRAVENOUSLY," do you
4 see that it says, "Sedation/anxiolysis/amnesia for
5 procedures"?

6 A. Procedures -- that's correct. Procedural
7 sedation.

8 Q. And that's what we've been talking about
9 in the context of RSI and cardiac catheterization?

10 A. This is in the context of, from what I saw
11 there, bronchoscopy, which is where they shove a
12 scope down the throat to look at the lungs. At
13 least that's what I'm reading.

14 Q. Okay. Well -- and is endoscopy a kind of
15 bronchoscopy procedure?

16 A. No, bronchoscopy is specific to putting a
17 camera down the throat and looking at the lungs.
18 Endoscopy, from my understanding, is putting a
19 camera down the esophagus to look at the esophagus
20 and stomach.

21 Q. A bronchoscopy is a different procedure,
22 in your opinion.

23 A. Bronchoscopy is specific for broncho,
24 which is lung. Endoscopy, or endo, is for the GI
25 system. They're two different organ systems.

1 Q. Did you see that it says for bronchoscopy
2 procedures, the use of a narcotic premedication is
3 recommended?

4 A. That's correct.

5 Q. Why is the use of a narcotic premedication
6 recommended?

7 A. It says right there, because they're using
8 a reduction in dosage of midazolam. Reduction is
9 less, not more.

10 Q. Are you referring to the first sentence
11 after the colon in this paragraph that reads,
12 "Narcotic premedication results in less variability
13 in patient response and a reduction in dosage of
14 midazolam"?

15 A. That's correct, less drug.

16 Q. And what --

17 MR. SUTHERLAND: I'm sorry, Ms. -- I'm
18 sorry, where are we?

19 MS. NELSON-MAJOR: We're in the
20 paragraph that's titled: INTRAVENOUSLY.

21 MR. SUTHERLAND: Right.

22 MS. NELSON-MAJOR: And under that
23 there's a sentence that states,
24 "Sedation/anxiolysis/" --

25 MR. SUTHERLAND: Got you.

1 MS. NELSON-MAJOR: -- "amnesia for
2 procedures."

3 MR. SUTHERLAND: Yeah.

4 MS. NELSON-MAJOR: And I'm directing
5 Dr. Patel to the sentence that reads,
6 "Narcotic premedication results in less
7 variability in patient response and a
8 reduction in dosage of midazolam."

9 MR. SUTHERLAND: Got it.

10 BY MS. NELSON-MAJOR:

11 Q. What does patient response mean in this
12 context?

13 A. Well, patient response means just how the
14 patient responds and what clinical effect it will
15 have on them in regards to the therapeutic dose
16 range administered.

17 Q. And then the next sentence says, "For
18 peroral procedures, the use of an appropriate
19 topical anesthetic is recommended."

20 Why is a topical anesthetic recommended
21 when midazolam is used for a peroral procedure?

22 A. For the placement of the ET tube, as time
23 allows, they would use topical lidocaine.

24 Q. And why if time allows would you use
25 topical lidocaine?

1 A. It actually goes to the procedure itself,
2 so -- I'm not sure if you're familiar. But from my
3 observation, the topical lidocaine isn't something
4 you dump in the throat; they have to actually draw
5 it up in a syringe, and then you use what's called
6 an atomizer, attach it to the end of the syringe,
7 and then it's sprayed.

8 It allows the plastic tube to glide into
9 the throat, to minimize as much as possible the
10 coughing, gagging, and offer a little bit of -- very
11 little, if any, pain support while they're doing a
12 procedure.

13 Q. And how does the lidocaine ensure that the
14 tube -- I think you said to guide the tube down the
15 throat? Is that what you meant?

16 A. No, the topical lidocaine is administered
17 before the tube is placed. To guide the tube
18 placement is via a laryngoscope, with a handle. So
19 the blade actually has a light at the end of it.
20 And that opens up the patient's -- from my
21 understanding and observation, their throat and then
22 they place the tube.

23 The topical lidocaine is sprayed and
24 administered before they do that. But it doesn't
25 come that way, it comes as a liquid. So from what

1 I've observed, you have to actually draw it up in a
2 syringe, put an atomizer, which is a particle
3 reducer, at the end of the syringe, if you have one,
4 to actually get the drug to where you want it to go,
5 at the right dose, at the right time, all before --
6 within seconds of placing the tube.

7 That's why I said, it's not always done,
8 nor do you have time for it.

9 Q. But when you have time for it, you
10 administer the lidocaine to reduce the patient's
11 response to the pain and noxious stimulus of the
12 tube being inserted?

13 A. That's correct, that can be done in a
14 therapeutic and controlled setting.

15 Q. And so moving on to the second use of
16 midazolam that you identified in your report, as an
17 "induction agent." What do you mean by "induction
18 agent"?

19 A. It's given prior to the start of
20 anesthesia.

21 Q. And induction of anesthesia is different
22 than maintenance of anesthesia, correct?

23 A. I would defer to an anesthesiologist. I
24 don't have an opinion on that.

25 Q. But do you have an opinion on the use of

1 midazolam as an induction agent in anesthesia?

2 A. No. Negative. I just said it's used as
3 an induction agent because it is.

4 Q. But you don't know whether it's used or
5 not to maintain general anesthesia?

6 A. I'm not an anesthesiologist. I don't
7 administer the drug. So I defer to an
8 anesthesiologist.

9 Q. I'm just trying to understand how you're
10 able to offer an opinion on the appropriate use of
11 midazolam as an induction agent but not whether or
12 not it's an appropriate agent to be used for
13 maintenance of anesthesia. Can you help me
14 understand why one falls within your expertise and
15 one doesn't?

16 A. They're both referenced. My experience
17 and what I've viewed and my practice over the 20
18 years is that it's commonly used as an induction
19 agent. That's why that's my opinion. And it's
20 actually cited as an approved use. It's not
21 anything new.

22 Q. And you have no opinion on whether
23 midazolam is capable of maintaining general
24 anesthesia at any dose?

25 MR. SUTHERLAND: Objection to form.

1 THE WITNESS: Maintenance of general
2 anesthesia? No, I defer to an
3 anesthesiologist.

4 BY MS. NELSON-MAJOR:

5 Q. Earlier you referred to deep sedation, as
6 opposed to conscious sedation; is that right?
7 They're two distinct categories?

8 MR. SUTHERLAND: Object to the form.

9 THE WITNESS: Conscious sedation would
10 be having the patient almost fully awake and
11 responsive during the procedure. And,
12 correct, when they're on the mechanical
13 ventilator, sometimes that calls for a deeper
14 level of sedation, that's true.

15 BY MS. NELSON-MAJOR:

16 Q. I want to ask you a couple of questions
17 about vecuronium bromide. What class of drugs does
18 vecuronium bromide fall within?

19 A. It would be neuromuscular blockers.

20 Q. And on page nine of your report, under
21 "Pharmacologic properties" -- do you see that
22 subheading?

23 A. I do, yes.

24 Q. You wrote, "After administration the
25 vecuronium will take effect within two [to] three

1 minutes."

2 What do you mean by "take effect" in this
3 sentence?

4 A. In a therapeutic setting, at that dose, it
5 would have neuromuscular blocking properties within
6 a two-minute timeframe.

7 Q. So you're not talking about peak effect,
8 are you, when you say it'll take effect within two
9 to three minutes?

10 A. This would be -- because it is a fairly
11 rapid-acting drug, comparative to the sedatives, it
12 peaks, and would easily, within two minutes, you'd
13 have full neuromuscular blockade. The peak's going
14 to be a lot -- the onset is faster than the peak; if
15 it wasn't, you wouldn't be waiting two or three
16 minutes to perform an intubation.

17 Q. Does the two-to-three-minute window change
18 with different doses?

19 A. I don't believe it'll change all that much
20 with a different dose, for this particular drug.

21 Q. So, in your opinion, onset times are not
22 progressively shorter with higher doses of
23 vecuronium?

24 A. There are a couple of papers that have
25 referenced a faster onset time as the dose is

1 escalated, that's correct, that's been published.

2 Q. And do you agree with those studies?

3 A. That it's faster the higher the dose
4 administered? That's correct. The same is said for
5 midazolam.

6 Q. And what do you base your opinion that the
7 vecuronium bromide will take effect within two to
8 three minutes after administration?

9 A. It's not my opinion, that's what's cited
10 in the product labeling and in the references, for
11 that dose, for that scenario.

12 Q. Are all --

13 A. Sorry, go ahead.

14 Q. No, my apologies, I thought you were done.
15 Please finish.

16 A. No, it's -- the reason I point that out,
17 and make a point to do this for a second, is that
18 it's clear -- for example, if you go back to the
19 midazolam pack product labeling, it has effect of --
20 there's places in the product labeling where it says
21 one to two minutes, two to three minutes, 30 to 60
22 seconds. So it is dose dependent. But that's why I
23 mention that.

24 Q. Are all muscle groups impacted at the same
25 time following administration of vecuronium bromide?

1 A. It acts on the neurotransmitter
2 acetylcholine and blocking it. So my opinion is,
3 yes, that will take place all relatively at the same
4 time.

5 Q. Have you ever dispensed vecuronium bromide
6 for use on a patient?

7 A. In the clinical context for patient care,
8 I have, yes.

9 Q. For what purposes?

10 A. Neuromuscular blockade.

11 Q. And at what doses?

12 A. You don't dis-- I'm sorry, the question
13 doesn't make sense. You don't dispense a dose, you
14 dispense the vial or the syringe.

15 Q. So you don't fill a prescription for a
16 certain dosage?

17 A. No. I apologize, the question doesn't
18 make sense. You dispense the syringe or the
19 premanufactured vial.

20 Q. When a prescription is written and you
21 receive that prescription, does it tell you what the
22 dose to be administered will be?

23 A. Negative, because the provider will
24 dictate the dose and how many doses they'll need to
25 give, whether it's one timed dose or in increments,

1 depending on the situation.

2 Q. How do you know how many vials to provide
3 then?

4 A. I'm sorry, the question doesn't make
5 sense. The vials are already there at the
6 provider's hands. They're diluting and
7 administering it on site depending on how much they
8 need. Are you asking for what a normal dose is?

9 Q. I'm asking for what the clinical range of
10 doses are that you've given of vecuronium bromide in
11 your clinical experience.

12 A. I have never given vecuronium bromide to a
13 patient. I've dispensed it for a patient. Is that
14 what you're asking, for the therapeutic dosage
15 range? I'm sorry, I don't understand.

16 Q. My question is, the vecuronium bromide
17 that you've dispensed to a patient in a clinical
18 setting, what is the clinical range of doses of
19 vecuronium bromide?

20 A. The clinical range would be 0.04 milligram
21 if it's just a bolus up to 0.1 milligram per
22 kilogram, depending on the scenario, and if they're
23 re-dosing and it it's a one-time dose. At least
24 that's been my understanding and experience. Which
25 would be encompassed in less than one 10-milligram

1 vial.

2 Q. Have you ever seen vecuronium bromide
3 administered to a patient without an anesthetic or
4 analgesic?

5 A. Have I seen vecuronium --

6 MR. SUTHERLAND: Object to the form.

7 THE WITNESS: Oh, sorry, go ahead.

8 MR. SUTHERLAND: Object to the form.

9 You can answer.

10 THE WITNESS: Sorry, could you repeat
11 the question?

12 BY MS. NELSON-MAJOR:

13 Q. Have you been present when a medical
14 professional has administered vecuronium bromide to
15 a patient without first giving them a premedication
16 of an anesthetic or an analgesic?

17 A. No. I don't have an opinion. I don't
18 think I've ever been present when that's happened.

19 Q. Does administration of the vecuronium
20 bromide without an anesthetic agent cause pain?

21 MR. SUTHERLAND: Object to the form.

22 THE WITNESS: I don't have an opinion.

23 I can't answer that. I've never been present
24 when they've administered.

25

1 BY MS. NELSON-MAJOR:

2 Q. What I'm asking is, does the
3 administration of vecuronium bromide cause pain on a
4 patient? I'm not asking whether you've been
5 present.

6 A. Oh, I'm sorry, I didn't understa-- because
7 your first question was, when you were present and
8 they didn't give the pre-anesthetic, does it cause
9 pain. So that's why I was confused. So you want to
10 know if it's given -- I don't understand your
11 question.

12 Q. My first question was, and you've answered
13 it, was have you ever seen vecuronium bromide
14 administered without an anesthetic or analgesic
15 premedication, and you said no.

16 My new question is, does administration of
17 vecuronium bromide without a premedication of an
18 analgesic or anesthetic cause pain to a patient?

19 A. Does a therapeutic dose of vecuronium
20 cause pain to a patient --

21 Q. Yes.

22 A. -- within out the pre-anesthetic?

23 Q. Yes.

24 A. I'm not sure it would cause pain. It
25 depends on what they're doing if they didn't give

1 the pre-anesthetic. It would leave them paralyzed.

2 Q. And if a patient was not given an
3 analgesic or a sedative drug before that vecuronium
4 bromide was given, what would that feel like to a
5 patient?

6 A. They would be aware of their surroundings
7 and the surgery.

8 Q. And would they be aware of their
9 paralysis?

10 A. I'm not sure they'd be aware of the
11 paral-- they'd just be paralyzed. So, yeah, I guess
12 they would be aware that they can't move their
13 extremities.

14 Q. And if they were given a sufficient enough
15 dose that their breathing muscles were affected,
16 would they experience air hunger?

17 A. It would be air hunger and/or death if the
18 airway isn't supported, which unfortunately has
19 occurred in medication errors, one recently,
20 actually.

21 Q. And on page nine of your report you write,
22 "As vecuronium does not affect the level of
23 consciousness it is recommended to administer an
24 anesthetic sedative prior to vecuronium."

25 Why is it recommended that an anesthetic

1 sedative be administered prior to vecuronium?

2 A. It's to depress the level of consciousness
3 and awareness.

4 Q. And why would you want to depress the
5 level of consciousness or awareness before
6 administering vecuronium bromide?

7 A. In the rapid sequence intubation, it's so
8 that they're not aware that they're paralyzed, so
9 that the provider or clinician can carefully put in
10 placement for the airway support, or the plastic
11 tube.

12 Q. And why in a clinical setting would you
13 want to prevent a patient from being aware of the
14 fact that they're being paralyzed?

15 A. It's been described that they would feel
16 trauma, when they were questioned after being
17 awakened.

18 Q. And trauma from what?

19 A. I believe they referred to it as
20 post-traumatic stress disorder. So they could have
21 nightmares or visions or dreams.

22 Q. And you wrote that it's recommended that a
23 premedication anesthetic be given before the
24 vecuronium. Where does that recommendation come
25 from?

1 A. I believe it's from the product labeling.
2 But any of the clinical guidelines in critical care
3 or anesthesia likely discuss the same principle, in
4 a therapeutic context.

5 Q. Once the vecuronium bromide has taken
6 effect, will an inmate be able to move or signal if
7 they're experiencing pain during execution?

8 A. I don't believe at this dose, at the
9 500-milligram dose of midazolam, again, given in
10 250-milligram increments intravenously, and after
11 vecuronium bromide is administered, will the inmate
12 be able to signal, no.

13 Q. And that's because they're paralyzed?

14 A. That's because of the first drug
15 administered in the protocol.

16 Q. What I'm asking is, if a patient does in
17 fact experience pain -- and I'm asking you to assume
18 that in this hypothetical -- will they be able to
19 signal pain following administration of the
20 vecuronium bromide?

21 A. That's dependent on the midazolam dose.

22 Q. And if, say, a vein was to rupture and the
23 midazolam didn't make it into the vascular
24 circulation and the person did not receive the full
25 dose of midazolam, or even any midazolam, following

1 the vecuronium bromide would that person be able to
2 signal if they were experiencing pain?

3 A. Well, that would be difficult to hypo-- in
4 a hypothetical, because you would see that amount
5 of 50 to 100 cc's of fluid sitting in their arm, so
6 you wouldn't administer the vecuronium.

7 Q. What class of drugs does potassium
8 chloride fall within?

9 A. Potassium chloride is considered an
10 electrolyte.

11 Q. And have you dispensed potassium chloride
12 for a medical professional to administer to a
13 patient?

14 A. I have, yes.

15 Q. And for what purposes?

16 A. It's to therapeutically replace a
17 potassium loss either in the context of diuresis or
18 fluid loss or potassium wasting that occurs from
19 GI loss or diarrhea, or in the context of
20 cardioplegia where they in fact get a potassium
21 vial.

22 Q. And what's cardioplegia?

23 A. Cardioplegia is the fluid a perfusionist
24 uses during bypass surgery.

25 Q. And during bypass surgery, is potassium

1 chloride used to stop the heart from beating?

2 A. That's correct, that's its intended
3 purpose after the aorta is clamped off, the
4 cardioplegia is infused.

5 Q. And in a clinical setting, what is the
6 maximum concentration at which potassium chloride is
7 given?

8 A. It depends on which clinical setting.

9 Q. Out of those clinical scenarios you just
10 outlined, which of those clinical scenarios uses the
11 highest concentration of potassium chloride?

12 A. It's actually the one where you're just
13 replacing it from potassium lost, because the
14 cardioplegia one could be 40 mil equivalents or more
15 in a liter, the others are 20 to 40 mil equivalents
16 in 100 mLs of fluid.

17 Q. Is an injection of a clinical dose and
18 clinical concentration of potassium chloride painful
19 if the patient isn't adequately sedated?

20 A. From my background, training and
21 experience and from seeing nurses give it at the
22 bedside, patients experience a sting, most reflect
23 on it as a mosquito bite.

24 Q. What about a bolus dose of 250 mil
25 equivalents as called for by the protocol, what

1 would that feel like?

2 MR. SUTHERLAND: Object to the form.

3 THE WITNESS: I don't know what it'd
4 feel like. I don't know if that's ever been
5 studied nor ethically done in a patient care
6 context.

7 BY MS. NELSON-MAJOR:

8 Q. I'm going to pull up the potassium
9 chloride labeling that you cited in your report.
10 And Ms. Leonard will e-mail that to Mr. Sutherland.

11 MR. SUTHERLAND: Got it, and on its
12 way.

13 A. Okay, this one was vecuronium. Is that
14 what you're -- is that the one you're talking about?

15 Q. I might have misspoke. I meant to pull up
16 the potassium chloride product labeling.

17 MS. LEONARD: One second. I'll send
18 that right now.

19 MR. SUTHERLAND: Dr. Patel, are you
20 thinking you're going to be good on the
21 meeting?

22 THE WITNESS: Yeah, I was just
23 checking. That's fine.

24 MR. SUTHERLAND: I just got it, and
25 it's on its way.

1 THE WITNESS: I got it. Okay.

2 BY MS. NELSON-MAJOR:

3 Q. Is this the potassium chloride product
4 labeling you cite in your report?

5 A. That is the one referenced, that's
6 correct.

7 Q. I'm going to mark this as Exhibit 15, and
8 ask you to turn to page five. Take a look at the
9 first highlighted sentence.

10 A. Okay.

11 Q. So it states that, "Administration via a
12 central route is recommended for dilution by the
13 blood stream and avoidance of extravasation, as well
14 as to avoid the pain and phlebitis associated with
15 peripheral infusion."

16 What does extravasation mean?

17 A. That's what we talked about earlier when,
18 I believe -- and I respectfully disagree with
19 Dr. Almgren and Dr. Stevens when they were
20 commenting on the pH of midazolam being extremely or
21 excruciatingly painful, which has nothing to do with
22 it. It actually has to do with extravasation. And
23 extravasation is when the drug gets outside of a
24 vessel.

25 Q. And what does phlebitis mean?

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1 A. Phlebitis is kind of an umbrella term for
2 inflammation of the vessel.

3 Q. When potassium chloride is administered at
4 your work, is it generally administered via a
5 central route?

6 A. It's patient dependent. I would say the
7 majority is actually administered, more than
8 50 percent, peripheral. It's because there's
9 actually a number of cautions and dangers associated
10 with central lines, one of those being infection.

11 Q. And why does the product labeling
12 recommend central route administration despite those
13 concerns?

14 A. It has to do with the thickness of the
15 vessel. So, many times the peripheral vessel in the
16 hospital is the antecubital fossa, which I believe
17 is the main vein in the inner elbow, which is what
18 is used in the TDOC protocol, I believe.

19 Q. I'm not understanding the connection
20 between the size of the peripheral vein and this
21 warning in the potassium chloride monograph. Can
22 you explain to me why the product labeling says that
23 potassium chloride should be administered via the
24 central route?

25 A. Sure. It has to do with the thickness of

1 the blood vessel, and it has to do with the amount
2 of dilution that occurs with the drug after
3 administered. In a therapeutic setting, as I
4 mentioned, more than 60, 70 percent is peripheral,
5 and it's because of the risks and the safety
6 associated with central line placement.

7 Q. So do you disagree with this
8 recommendation in the product labeling that
9 potassium chloride should be administered via
10 central route?

11 MR. SUTHERLAND: Object to the form.

12 THE WITNESS: No, I never said I
13 disagree with it. I'm telling you what
14 happens around hospitals all over the country.

15 BY MS. NELSON-MAJOR:

16 Q. Do you -- what is the connection between
17 the size of the peripheral vein and why this product
18 labeling makes the recommendation that the potassium
19 chloride be administered by a central route?

20 A. In a therapeutic dose the idea and thought
21 is, is that the pain and phlebitis is minimized with
22 the central vein administration, it doesn't
23 eliminate it.

24 Q. And you described the pain and phlebitis
25 as a mosquito bite; is that correct?

1 A. That's correct. And that wasn't my
2 description, that's what patients have said.

3 Q. Why would a product labeling recommend a
4 central route to avoid the pain associated that's
5 comparable to a mosquito bite?

6 MR. SUTHERLAND: Object to the form.

7 THE WITNESS: I don't know. You'd have
8 to ask the FDA, who approved the verbiage for
9 the product labeling, and Baxter.

10 BY MS. NELSON-MAJOR:

11 Q. And then the next sentence that's
12 highlighted reads, "The highest concentrations of
13 Potassium Chloride Injection (300 mEq [per] liter
14 and higher) should be exclusively administered via
15 central intravenous route."

16 What is 300 mil equivalents per liter in
17 terms of mil equivalents per milliliter?

18 A. That would be -- oh, sorry, go ahead.

19 MR. SUTHERLAND: Object to the form.

20 THE WITNESS: In terms of milliliters,
21 you would divide it by a thousand, so it'd be
22 0.3 mil equivalents per mL.

23 BY MS. NELSON-MAJOR:

24 Q. So according to the product labeling, if
25 you're going to administer a potassium chloride

1 injection of higher than .3 mEq per mL, it should be
2 done exclusively via central route; is that correct?

3 A. That's correct, as suggested by the -- and
4 approved by the FDA in the context of treatment and
5 healing.

6 Q. And what is the concentration of potassium
7 chloride that TDOC uses during an execution?

8 A. The concentration, if I recall correctly,
9 is 120 mil equivalents in 60 mL.

10 Q. Would that be 2 mEq per mL?

11 A. That's correct.

12 Q. And that's much higher than .3 mEq per mL?

13 A. That's correct.

14 Q. And why is the recommendation stated more
15 strongly in the context of the high concentrations
16 of potassium chloride in the product labeling?

17 MR. SUTHERLAND: Object to the form.

18 THE WITNESS: Sure. It's because this
19 is reviewed in the context of efficacy and
20 patient safety in the context of treatment and
21 healing. And so that's what the FDA deemed
22 appropriate for direct patient care.

23 BY MS. NELSON-MAJOR:

24 Q. And what I'm trying to understand is, what
25 the pharmacological difference between a highest

1 concentration of potassium chloride and a standard
2 concentration of potassium chloride that would lead
3 the FDA to approve a recommendation that the high
4 doses be exclusively administered via central line.

5 A. Well, my opinion, just my opinion, the
6 recommendation doesn't actually make any sense.
7 Because if we listen to what we're talking about,
8 300 mil equivalents in a liter in a therapeutic
9 setting or in the setting of diagnosis, care and
10 healing, per liter is only utilized in cardioplegia.
11 Cardioplegia generally ranges from 40 to 80 mil
12 equivalents in a liter.

13 In therapeutic setting and patients that
14 are on the floor, if you're familiar, are generally
15 in 20 and 40 mil equivalents in 100 mL. You would
16 never approach 300 mil equivalents in a liter
17 anyway.

18 Q. Well, my question is, why is the
19 recommendation more strongly asserted for a higher
20 concentration? Setting aside the actual number
21 value associated with the higher concentration.

22 A. I couldn't -- I don't have an opinion. I
23 don't -- I haven't reviewed what the FDA's reviewed.
24 You'd have to ask them.

25 Q. So from a pharmacological standpoint, you

1 don't have an answer to why a higher concentration
2 would warrant increased precautions in
3 administration to a patient?

4 A. No, from a pharmacologic perspective, I'm
5 telling you, therapeutically, I have never seen 300
6 mil equivalents in a liter. So that's why I have no
7 opinion on it.

8 Q. I'm not asking about the value stated.
9 I'm asking whether, as you increase the
10 concentration of potassium chloride for
11 administration to a patient, there's increased
12 safety risks attendant with that increased
13 concentration.

14 A. That's a different question. So, yes,
15 there is. That's why they recommend central access.

16 Q. And what of those increased safety risks?

17 A. The safety risk is pain and phlebitis, as
18 they stated above.

19 Q. And so that risk of pain and phlebitis
20 increases as the concentration increases?

21 A. That's correct, in this therapeutic
22 setting.

23 Q. Does the risk of pain and phlebitis with
24 an increased dose not occur in a non-clinical
25 setting?

1 MR. SUTHERLAND: Object to form.

2 THE WITNESS: Yeah, the question
3 doesn't make sense, because you don't
4 pre-medicate patients getting potassium
5 chloride. So I don't understand the question.

6 MS. NELSON-MAJOR: My question -- court
7 reporter, could you read back my last -- not
8 this last question but the previous question,
9 and the previous answer, please.

10 (The requested portion was read
11 back by the reporter.)

12 THE WITNESS: That's my answer.

13 BY MS. NELSON-MAJOR:

14 Q. Well, let me clarify, because I'm not sure
15 that my question was clear to you then. I asked
16 whether the risk of pain and phlebitis increases
17 with higher concentrations of potassium chloride.
18 And your answer was, yes, in this clinical setting.
19 And I'm trying to figure out the significance of the
20 clinical setting piece of your answer.

21 A. The significance is, is exactly what we're
22 talking about. If you're familiar with patients
23 getting 20, 40 or 60 mil equivalents of potassium
24 chloride, zero of them are pre-medicated; meaning,
25 they are fully conscious and aware of anything,

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1 that's why they describe the pain.

2 Q. And in those doses, what are the
3 concentrations you're discussing? So I'm asking a
4 question about concentration, not about dose right
5 now.

6 A. Sure. It could be 40 mil equivalents in
7 100 mL or 20 mil equivalents in 100 mL. So that
8 would be 0.2 mil equivalent for an mL.

9 Q. And that's lower than the concentration of
10 potassium chloride that TDOC uses at an execution,
11 correct?

12 A. Obviously, yes.

13 Q. Could you, please, scroll to page seven of
14 the product labeling.

15 A. Okay.

16 Q. And do you see at the bottom portion of
17 the page where it states, "General Disorders And
18 Administration Site Conditions"?

19 A. That's correct.

20 Q. And it lists chest pain, infusion site
21 pain, infusion site irritation, and burning
22 sensation?

23 A. That's correct.

24 Q. And do you agree with those warnings?

25 MR. SUTHERLAND: Object to the form.

1 THE WITNESS: I'd agree that those are
2 post-market adverse reactions, that's correct.

3 BY MS. NELSON-MAJOR:

4 Q. Let me go back to page one of your report.

5 A. Okay.

6 Q. I'm looking at the third paragraph in the
7 Introduction section. The paragraph begins, "It is
8 my opinion." Do you see that?

9 A. I do, yes.

10 Q. And then the second sentence reads,
11 "Instead, based upon the chemicals used, the
12 preparation, the dose and order of administration,
13 the Protocol will result in the inmate being
14 insensate during the transition to death."

15 What does "transition to death" mean here?

16 A. The act of dying.

17 Q. What point in the process as laid out by
18 the protocol are you referring to when you use the
19 term "transition to death"?

20 MR. SUTHERLAND: Objection to the form.

21 THE WITNESS: Which part of the
22 protocol -- I don't understand the question.

23 The protocol is designed to cause death.

24 BY MS. NELSON-MAJOR:

25 Q. I'm very much aware of that fact. My

1 question is, when you say, "the Protocol will result
2 in the inmate being insensate during the transition
3 to death," I'm trying to understand at what
4 temporal point in the execution process you're
5 saying the inmate will become insensate.

6 A. It would be after the administration of
7 midazolam.

8 Q. And then on page 14 -- if you could scroll
9 to that page, please.

10 A. Okay.

11 Q. And I'm looking for the exact sentence.
12 So at paragraph number two that begins, "My opinion
13 is that following." Do you see that?

14 A. I do.

15 Q. So you wrote that, "My opinion is that
16 following administration of the three chemicals as
17 provided in the Protocol will result in the inmate
18 being insensate."

19 Is it your opinion that the inmate will
20 become insensate after the third drug is
21 administered?

22 MR. SUTHERLAND: Objection to the form.

23 THE WITNESS: That they will be
24 insensate after the administration and
25 completion of the first drug, which would be

1 midazolam.

2 BY MS. NELSON-MAJOR:

3 Q. And then you explain the basis for this
4 opinion throughout this paragraph. And I want to
5 ask you about the sentence where you write,
6 "Midazolam injection demonstrates a dose-dependent
7 effect (higher the dose [arrow] higher the effect)
8 on the level of consciousness."

9 Is this dose-dependent effect limited by
10 the ceiling effect we talked about earlier?

11 A. It would be limited by the ceiling effect
12 if the ceiling effect is known, that's correct.

13 Q. And you earlier testified that in your
14 experience and expertise, it was your belief that
15 midazolam, like all benzodiazepines, have a ceiling
16 effect?

17 A. The concept and the principle is
18 applicable to benzodiazepine, that's correct. I'm
19 not aware of any published literature that says what
20 the dose is.

21 Q. And then building on this statement, you
22 write that, "Midazolam has been demonstrated to
23 effect experiences of pain in a dose-dependent
24 fashion."

25 We already talked about the sentence a bit,

1 and you cited the Wang article in support. Are
2 there other studies or articles that you're relying
3 on for the proposition that midazolam has been
4 demonstrated to effect experiences of pain, as
5 opposed to the anticipation of pain?

6 MR. SUTHERLAND: Object to the form.

7 THE WITNESS: Not other than what we've
8 already discussed, no.

9 BY MS. NELSON-MAJOR:

10 Q. And then moving down into page 15, you
11 write that midazolam is an appropriate drug for
12 lethal injection because it "disrupts the pathways
13 of neuronal (electrical) activity between the key
14 regions of the brain integrated to the perception
15 and anticipation of pain." And, again, here you
16 state --

17 MR. SUTHERLAND: I'm sorry, Ms. Nelson-
18 Major, you say -- you started off saying,
19 "midazolam is an appropriate drug for lethal
20 injection." Where are you reading from?

21 MS. NELSON-MAJOR: I am reading from
22 the top of page 15, the second full sentence,
23 and it states, "Midazolam" --

24 MR. SUTHERLAND: Okay. "As midazolam
25 is"?

1 MS. NELSON-MAJOR: No, the preceding
2 one.

3 THE WITNESS: The one before it, yeah.

4 MR. SUTHERLAND: Okay. Okay.

5 MS. NELSON-MAJOR: Do you see where we
6 are?

7 MR. SUTHERLAND: "Midazolam disrupts"?

8 BY MS. NELSON-MAJOR:

9 Q. "Midazolam disrupts the pathway of
10 neuronal (electrical) activity between the key
11 regions of the brain integrated to the perception
12 and anticipation of pain; therefore, it is an
13 appropriate drug for lethal injection." Do you see
14 where we are, Dr. Patel?

15 A. Yes.

16 Q. And again you cite the Wang article for
17 this proposition. Besides the Wang article, are
18 there other studies or articles that support this
19 proposition that you're relying on?

20 A. Outside of that, no. Because we don't
21 have a paper evaluating in a therapeutic context
22 500 milligrams of midazolam.

23 Q. That's not what my question was. The
24 statement that you've made here is that, "Midazolam
25 disrupts the pathways of neuronal activity between

1 the key regions of the brain integrated to the
2 perception and anticipation of pain."

3 My question is, besides Wang, do you have
4 other articles or studies that you're supporting --
5 excuse me, that you're citing to support this
6 proposition?

7 A. Other than anything referring to midazolam
8 in my references, no.

9 Q. Then you state, "As midazolam is an
10 acceptable first drug for RSI to facilitate a
11 depressed level of consciousness, more likely than
12 not it is acceptable to administer prior to
13 vecuronium."

14 In your clinical practice, would you
15 recommend the use of a drug on the basis that you
16 thought it was more likely than not acceptable?

17 A. Absolutely. It's still used today and
18 it's used by anesthesiologists all over the country,
19 from what I've read and what I'm aware of.

20 Q. How confident are you in this opinion that
21 because midazolam's an acceptable first drug for
22 RSI, it's acceptable to administer prior to
23 vecuronium in this case?

24 A. How confident am I? Well, if we take a
25 step back and look at the therapeutic use of

1 midazolam, if it was not appropriate, which is what
2 you're obviously insinuating and proposing, it would
3 be ripped out of every textbook and every
4 anesthesiology reference and every hospital for this
5 indication, and it's not. So it is appropriate more
6 likely than not.

7 Q. Dr. Patel, I'm not trying to insinuate
8 anything. I'm just trying to understand your
9 inclusion of the phrase "more likely or not,"
10 because that's not a phrase you used when expressing
11 other opinions. So I'm just trying to understand
12 whether you hold this opinion with a less degree
13 of confidence than you hold the other opinions
14 throughout your report.

15 A. No, there's no less degree of confidence
16 than any of the other opinions.

17 Q. And are you saying that rapid sequence
18 induction involves the same level of sedation
19 necessary to render an inmate insensate to the pain
20 and suffering of the second and third drug in the
21 protocol?

22 MR. SUTHERLAND: Objection to the form.

23 THE WITNESS: Based on the dosage and
24 route of administration and the procedure,
25 that's correct.

1 BY MS. NELSON-MAJOR:

2 Q. Do the studies you have in your opinion
3 involve the same level of stimulus or pain?

4 MR. SUTHERLAND: Objection to the form.

5 THE WITNESS: Repeat the question
6 again?

7 BY MS. NELSON-MAJOR:

8 Q. You're drawing a comparison between RSI
9 and TDOC's protocol for executing an inmate. And
10 I'm asking you whether you're also drawing a
11 comparison between the level of pain and suffering
12 that might be experienced in an RSI and that might
13 be experienced in an execution context.

14 MR. SUTHERLAND: Same objection.

15 THE WITNESS: The association and
16 reason that statement's in there is because
17 there is a lot of questions about, obviously,
18 midazolam being the first drug in the
19 protocol, is that in a clinical context even
20 it's appropriate. So if it's appropriate in
21 the clinical context, in the setting, in
22 depressed level of consciousness and
23 awareness, my opinion is that 500 milligrams
24 is more than appropriate and adequate in the
25 context that we're discussing.

1 I apologize if that's not what you
2 asked, but that's what I was understanding you
3 were asking.

4 BY MS. NELSON-MAJOR:

5 Q. So are you offering an opinion that the
6 level of sedation required for an RSI is the same
7 level of sedation required for the protocol to
8 render an inmate insensate to the second and third
9 drug?

10 MR. SUTHERLAND: Objection to the form.

11 THE WITNESS: Well, now you're mixing
12 -- it's apples and oran-- you're mixing --
13 it's not the same thing. One is a therapeutic
14 context. And, again, the reason it's in there
15 is that it's clear that even at a therapeutic
16 dose at a significantly lower amount, it's
17 appropriate to administer before a
18 neuromuscular blocker.

19 So, yes, it is appropriate to administer
20 in this setting at this dose for the intended
21 consequence. That's my opinion.

22 BY MS. NELSON-MAJOR:

23 Q. And for support for the comparison you
24 cite an article titled: "Neuromuscular blockade in
25 the critically ill," by Renew, et al. I'm going to

1 ask Ms. Leonard to send that article to
2 Mr. Sutherland. And while we're waiting for that
3 e-mail to arrive to Mr. Sutherland, I just have one
4 more question.

5 In the rapid sequence intubation context,
6 patients aren't administered potassium chloride
7 after the vecuronium bromide; is that correct?

8 A. Your question is, are patients
9 administered potassium chloride after rapid sequence
10 intubation?

11 Q. Yes.

12 A. I'm sorry, that doesn't make any sense,
13 because that's an electrolyte replacement and your
14 main focus is on the airway. So, no, they're not
15 administered potassium chloride after. The main
16 focus is to stabilize the airway.

17 Q. And we discussed the sensation that a
18 patient might experience upon administration of the
19 potassium chloride as being painful; is that
20 correct?

21 MR. SUTHERLAND: Object to the form.

22 THE WITNESS: That's correct, that has
23 been described.

24 BY MS. NELSON-MAJOR:

25 Q. And with increasing levels of noxious

1 stimuli are increasing levels of sedation required?

2 MR. SUTHERLAND: Object to the form.

3 THE WITNESS: As increasing levels of
4 noxious stimuli, are increasing levels of
5 sedation required. In what context?

6 MS. NELSON-MAJOR: In the clinical
7 context.

8 THE WITNESS: And what's the noxious
9 stimuli?

10 BY MS. NELSON-MAJOR:

11 Q. Well, starting with a conscious sedation,
12 you talked about cardiac catheterization. If we're
13 talking about open heart surgery, obviously an
14 increased level of sedation would be required for
15 that, correct?

16 A. That's correct. I wouldn't disagree with
17 that.

18 Q. And that's because the stimulus of having
19 an open heart surgery is greater than the stimulus
20 of having a cardiac catheterization; is that
21 correct?

22 A. Correct. I would say a saw going through
23 a chest is different than a catheter in the femoral
24 vein.

25 Q. And so following a rapid sequence

1 induction, if the doctor had to perform an
2 additional procedure on the patient, would
3 additional sedation need to be administered?

4 MR. SUTHERLAND: Object to the form.

5 THE WITNESS: It would depend on what
6 they're performing, I guess.

7 BY MS. NELSON-MAJOR:

8 Q. And if what they were performing was a
9 painful procedure, would additional levels of
10 sedation be required?

11 MR. SUTHERLAND: Object to the form.

12 THE WITNESS: I would default to the
13 physician. I don't know the procedure, is
14 it they're intubating before a cath or they're
15 intubating before cardiac surgery.

16 MS. NELSON-MAJOR: Mr. Sutherland, did
17 you receive that article?

18 MR. SUTHERLAND: I'm still waiting for
19 it.

20 MR. KURSMAN: I sent it a few minutes
21 ago, so hopefully it's --

22 MR. SUTHERLAND: Yeah, I still haven't
23 -- it still hasn't come through.

24 MS. NELSON-MAJOR: Maybe now would not
25 be a bad time to take a ten-minute break. We

1 can wait for that e-mail to come through
2 and --

3 MR. SUTHERLAND: Sure. Yeah.

4 VIDEOGRAPHER: Going off the record,
5 the time is 2:23.

6 (A brief recess was taken.)

7 VIDEOGRAPHER: Back on the record, the
8 time is 2:36.

9 BY MS. NELSON-MAJOR:

10 Q. Dr. Patel, before we took a break we were
11 talking about your opinion that midazolam is an
12 acceptable first drug in the lethal injection
13 protocol because it's used as the first drug in RSI,
14 and we were looking at this Renew article because
15 it's the article you support -- cite for support for
16 that proposition. Do you have that article in front
17 of you?

18 A. I do, yes.

19 Q. And I'm going to mark the Renew article as
20 Exhibit 16, I believe. Yeah, Exhibit 16.

21 Can you explain to me how this article
22 supports your conclusion that because midazolam is
23 the first drug in RSI, it's the appropriate first
24 drug in Tennessee's lethal injection protocol?

25 A. This particular paper references

1 neuromuscular blockade in a therapeutic context,
2 which is the same as -- in the ICU, which is the
3 same as RSI, in which midazolam is used as an
4 induction agent, or can be. Oh, sorry, go ahead.

5 Q. Please finish. I thought you were done.

6 A. There's two different premises. The RSI
7 is a one-time procedure, similar I guess in con-- in
8 some context to execution because it's a one-time
9 procedure. And in this particular circumstance,
10 this is comfort and sedation while the patient's
11 getting neuromuscular blockade, which midazolam is
12 also used for. It's just another use for the same
13 purpose and principle.

14 Q. And does this article specifically discuss
15 midazolam?

16 A. Does it specifically discuss midazolam?
17 No, it discusses neuromuscular blockade in the
18 critically ill, on the mechanical ventilator, the
19 different neuromuscular blockers and their dosages.

20 Q. And does this article discuss rapid
21 sequence induction?

22 A. It does not discuss rapid sequence
23 induction, no. That was the product labeling. It
24 does discuss sedation strategies, though.

25 Q. I want to turn to page nine.

1 A. Sure.

2 Q. I'd like to draw your focus to the
3 heading: Sedation strategies.

4 A. Okay.

5 Q. Do you see that section?

6 A. I do, yes.

7 Q. Do you see that it says, "A comprehensive
8 review of sedation strategies in the ICU is beyond
9 the scope of this review. Nonetheless, vigilance is
10 warranted in maintaining adequate sedation when
11 NMBA's are utilized in order to avoid unintended
12 patient awareness and recall."

13 And NMBA is neuromuscular blocking agent;
14 is that correct?

15 A. That's correct.

16 Q. And so how does this article that
17 explicitly states that they're not discussing
18 sedation strategies in the ICU support your
19 conclusion that midazolam's an appropriate drug for
20 TDOC to use?

21 A. It's just another description of how
22 neuromuscular blockers are used in the ICU. In this
23 case it's to facilitate mechanical ventilation.
24 We've already talked about the other ones that are
25 in the product labeling.

1 Q. And how does an article about use of a
2 neuromuscular blocking agent in the ICU support the
3 analogy you're drawing between RSI and the lethal
4 injection protocol?

5 A. It's not. They're all together. So in
6 order to utilize neuromuscular blockade in the ICU,
7 they're sedated. This article focuses specifically
8 on the neuromuscular blockers and their monitoring.

9 Q. And this article is explicitly stating
10 that they're not discussing what sedation is
11 necessary or adequate to protect against awareness
12 following a neuromuscular blocking agent, correct?

13 A. That's correct.

14 MR. SUTHERLAND: Object to the form.

15 THE WITNESS: That's correct. Go
16 ahead.

17 BY MS. NELSON-MAJOR:

18 Q. So how does an article that does that
19 address the adequacy of midazolam in the context of
20 TDOC's use of vecuronium bromide followed by
21 potassium chloride?

22 MR. SUTHERLAND: Objection to the form.

23 THE WITNESS: This is discussing long-
24 term neuromuscular blockade. The other one,
25 which is more relevant, is RSI which we've

1 already gone over.

2 BY MS. NELSON-MAJOR:

3 Q. But I'm asking you about this article
4 because you cited it for the proposition that
5 because midazolam is used as the first drug in RSI,
6 it is appropriate as the first drug in the lethal
7 injection protocol. And I'm trying to understand
8 how this article supports that analogy.

9 A. It's just describing another utilization
10 of neuromuscular blockers in the clinical context.
11 In this case it's for management in patients in the
12 unit.

13 Q. The opinion that you're offering comparing
14 RSI and the lethal injection protocol is made in
15 order to support your conclusion about the adequacy
16 of sedation in the protocol, correct?

17 MR. SUTHERLAND: Objection to the form.

18 THE WITNESS: The depth of the sedation
19 will be achieved based on the use of a
20 benzodiazepine before a neuromuscular blocker,
21 that's correct, as done in RSI.

22 BY MS. NELSON-MAJOR:

23 Q. And this article does not discuss sedation
24 strategies, correct?

25 MR. SUTHERLAND: Object to the form.

1 THE WITNESS: That's correct. This is
2 not a review of sedation analgesia. That's
3 discussed in the critical care medicine
4 guidelines, which were the PADIS guidelines
5 that got published in 2018.

6 BY MS. NELSON-MAJOR:

7 Q. And do you cite those guidelines in your
8 report?

9 A. Did I cite them? No. Are we aware of
10 them in clinical practice and do I use them daily?
11 Yes, absolutely.

12 Q. And are you saying that there's something
13 in those guidelines that support the comparison
14 you're drawing between RSI and the TDOC's lethal
15 injection protocol?

16 A. No, I'm saying that those guidelines
17 actually substantiate and support the use of
18 midazolam as a benzodiazepine for patients who are
19 neuromuscular blocked, in the ICU setting, on the
20 mechanical ventilator.

21 Q. And do those guidelines discuss whether
22 midazolam is an adequate sedative before
23 administering potassium chloride?

24 A. No, because that's outside of a clinical
25 context. There is not a study or a piece of

1 literature I'm aware of where clinicians are giving
2 midazolam, or any benzodiazepine, before potassium
3 chloride, or actually any drug, at least that I'm
4 aware of.

5 Q. And this Renew article, therefore, also
6 does not discuss sedation strategies prior to
7 administration of potassium chloride, correct?

8 A. That's correct. I've already stated, I'm
9 not aware of any medication trial in a clinical
10 context where a drug was given before a potassium
11 chloride infusion --

12 Q. And, in your opinion --

13 A. -- because it's not done.

14 Q. -- what would administration of 240 mil
15 equivalents of potassium chloride feel like to an
16 awake person?

17 MR. SUTHERLAND: Objection to the form.

18 THE WITNESS: I don't know what it
19 would feel like, because we don't do it in a
20 clinical context. I don't know if it's ever
21 been described.

22 BY MS. NELSON-MAJOR:

23 Q. Dr. Patel, are you a pharmacist or a
24 pharmacologist?

25 A. Both, by training and experience.

1 Q. And what's the difference between those
2 two fields?

3 A. Well, it's actually a continuum. If
4 you're familiar with pharmacy. So pharmacists
5 actually get six years of academia before going into
6 practice these days, and some colleges it's seven.
7 But the reason I mention that is, it's heavily
8 pharmacology focused, up to about three to four
9 years' worth, before they're put in the direct
10 patient care setting, where we interact with the
11 healthcare team and patients at the bedside or in at
12 outpatient setting.

13 Pharmacologists, because we -- I actually
14 have taught in that curriculum, is more laptop and
15 bench based, it's research; there's no human
16 interaction, there's no patients, but there is
17 teaching of the concepts, of which we've already
18 gone over, which are, again, the exact same in
19 pharmacology within pharmacy, which is
20 pharmacokinetics and pharmacodynamics, so how drugs
21 are broken down in the body and then,
22 pharmacodynamics, what their clinical impact is when
23 they're given.

24 Q. And are there different educational
25 requirements for a pharmacist versus a

1 pharmacologist?

2 A. They are two different degrees, that's
3 correct. Only one is recognized professionally.

4 Q. And what are the two different degrees?

5 A. Doctorate of pharmacy, which I possess,
6 and a doctorate of philosophy in pharmacology, which
7 is Ph.D. One is registered, one is not.

8 Q. What do you mean by registered?

9 A. We register and licensure and are
10 authorized individually by state. I'm not aware of
11 any professional regulation over pharmacologists.
12 So there's a big distinction, because we actually
13 work with patients.

14 Q. And in order to be registered as a
15 pharmacist you need a Pharm.D.; is that correct?

16 A. It would be Pharm.D., or two decades prior
17 it would be registered pharmacist or RpH, that's
18 correct, it would be one of the two.

19 Q. And how many years of graduate school did
20 it take for you to earn your Pharm.D.?

21 A. Well, it's -- to backtrack, it's a
22 lineage. So it was first the chem degree, which was
23 four years, the pharm degree -- Pharm.D. degree,
24 which was six, residency training added on an extra
25 year, seven, and a master's which I produced, went

1 thereafter, which was two years. So in total, gosh,
2 8, 12, 13 years of school.

3 Q. And what was your master's degree in?

4 A. Clinical research.

5 Q. And what was your undergraduate degree in?

6 A. Chemistry.

7 Q. And have you completed any coursework
8 since you attained your Pharm.D.?

9 A. Coursework? I'm not sure that I
10 understand. You mean like continuing education?

11 Q. I meant as far as you took classes to get
12 your Pharm.D. Did you take any other graduate-level
13 classes?

14 A. Besides my master's course, no. But
15 Pharm.D.'s, which are distinctly different from
16 Ph.D.'s, we have a requirement of CE, which is
17 continuing education, where you keep up on
18 scientific literature just like this.

19 Q. And how many hours a year are you required
20 to do your continuing ed?

21 A. It's 30 years (sic) of continuing
22 education ever year.

23 Q. Thirty hours per year?

24 A. That's what I recall and understand,
25 that's correct.

1 Q. And --

2 A. It varies by state.

3 Q. What states are you licensed in?

4 A. I'm licensed in the state of Illinois and
5 the state of Missouri, where I did my training.

6 Q. And you also hold several certifications;
7 is that right?

8 A. That's correct.

9 Q. And one is a BCPS, correct?

10 A. That's correct.

11 Q. And what is that certification?

12 A. It's Board Certified Pharmacotherapy
13 Specialist. It's again done by examination, and
14 then you actually have to submit 100 hours every
15 seven years of continuing education, unless you want
16 to subject yourself to taking the exam again. But
17 it revolves around therapy in the general sense of
18 adults, pediatrics, could be oncology, it could be
19 men's health, women's health, etcetera.

20 But it's, again, being certified to look at
21 those medications and how they interact with
22 laboratory values in the disease state and their
23 clinical outcome.

24 Q. And in order to first obtain that
25 certificate, you had to pass an exam?

1 A. That's correct, it requires licensure and
2 pass of examination. And thereafter, I thought it
3 was every seven years, you can either do -- you
4 could submit like 100 or 120 CE hours or, if you
5 want to, you could subject yourself to another exam.

6 Q. And is that certification specific to
7 sterile compounding?

8 A. Sterile compounding is included in there,
9 as well as total parenteral nutrition.

10 Q. Do you hold a Compounded Sterile
11 Preparations Certificate from the American Society
12 of Health System Pharmacists as well?

13 A. I do not, no.

14 Q. You also have a BCCCP; is that right?

15 A. That's correct.

16 Q. And what's that certificate?

17 A. Different than the first but the same
18 organization, it's board certification in critical
19 care pharmacotherapy. So it involves, encompasses
20 everything from the Intensive Care Unit in the
21 perioperative space, known as the operating room,
22 looking at the same things; again, the interaction
23 between laboratory values, medications and disease
24 states, and coming up with a therapeutic plan for
25 patients and communicating that with providers.

1 Q. And how did you obtain that certification?

2 A. That was -- it was first offered, if I
3 remember right, in twenty -- the fall of 2015. And
4 that was by examination as well. And that is coming
5 up for renewal at the end of this year.

6 Q. And is the renewal another exam?

7 A. That is one option. You can subject
8 yourself to the pleasure of another exam or you can
9 submit 100 hours.

10 Q. And what is your FCCP certificate?

11 A. It's fellowship credentialing and approval
12 in the College of Clinical Pharmacy, which is under
13 the organization of the American College of Clinical
14 Pharmacy, which encompasses a numerous of
15 therapeutic issues that we're discussing, in terms
16 of the drug activity and their action in patients
17 and/or preparations of drugs.

18 Q. And when did you first obtain that
19 certificate?

20 A. The fellowship, I was chosen and awarded
21 just this past fall. It would have been in 2020.

22 Q. And when you say awarded, how is that
23 awarding made?

24 A. Pharmacists can't just apply, you have to
25 be selected.

1 Q. And what about the FCCM?

2 A. That's a fellow in the College of Critical
3 Care Medicine, so that's within the Society of
4 Critical Care Medicine, which again encompasses the
5 adult Intensive Care Unit and therapeutic issues
6 within the perioperative space, known as the
7 operating room.

8 Q. Have you ever taken the Board of
9 Pharmacy's compounded sterile preparations specialty
10 certification exam?

11 A. No, I have not.

12 Q. And you're not a medical doctor, right?

13 A. No. And I'm okay not being one.

14 Q. And as a pharmacist, are you authorized to
15 write a prescription?

16 A. We are, actually, in the context of
17 collaborative practice agreements, that is true.

18 Q. And what is a collaborative practice
19 agreement?

20 A. It's where physicians actually will
21 authorize pharmacists to take over the prescription,
22 monitoring, and dosing of different medications
23 inside or outside of a hospital.

24 Q. And do those agreements authorize a
25 pharmacist to write a prescription for all drugs?

1 A. Negative. The collaborative practice
2 agreement would outline which medications.

3 Q. And are you part of a collaborative
4 services agreement?

5 A. We have collaborative privileges, that's
6 correct, for different services we offer in the
7 hospital in a therapeutic setting, that's correct.

8 Q. And so do you on occasion write
9 prescriptions for drugs?

10 A. It's not necessarily writing the
11 prescription for the drug, it's -- for example, the
12 physician can only type in one word in the computer,
13 not the dose, not the monitoring, not the laboratory
14 values, but the pharmacist takes over everything
15 after that one word or order is entered.

16 Q. And are those agreements generally limited
17 to a certain class of drugs?

18 A. It could be three, four, five, ten. It
19 depends on the hospital.

20 Q. And what is your services agreement for,
21 which drugs?

22 A. Ours are inclusive of antibiotics,
23 specifically vancomycin and aminoglycosides, and
24 it's also inclusive of an anti-coagulant warfarin,
25 or Coumadin.

1 Q. And are those the only two categories?

2 A. Those are the ones currently approved,
3 that's correct.

4 Q. And are you authorized to diagnose a
5 patient?

6 A. I guess -- I apologize, I don't understand
7 that. We don't -- I don't diagnose patients, no.

8 Q. Do you hold any other professional
9 licenses?

10 A. No, ma'am.

11 Q. Do you have any other medical training
12 outside of what we've already discussed?

13 A. No, ma'am.

14 Q. You're currently employed by the
15 University of Chicago Medicine system; is that
16 correct?

17 A. That's correct, yes, ma'am, I'm a
18 full-time clinician.

19 Q. And how long have you been employed by the
20 University of Chicago?

21 A. University of Chicago? It'll be -- I've
22 been there now two years.

23 Q. And what's your position there?

24 A. I'm within -- I'm a clinical coordinator
25 within the critical care and the perioperative

1 areas.

2 Q. And for the critical care area, are you
3 the only clinical pharmacist?

4 A. Oh, gosh, no. It's a busy hospital.
5 There's probably at least almost half a dozen of us.

6 Q. And what do your duties entail as a
7 clinical pharmacist for the critical care area?

8 A. It's direct patient care, so you work with
9 the nurse, the physician, sometimes a mid-level
10 provider. And it's reviewing the patient's
11 medications, their laboratory values, the disease
12 states, the notes in the chart, and coming up with a
13 therapeutic plan balancing the efficacy of the drug
14 and the safety.

15 Q. What percentage of your day is spent in
16 the pharmacy versus at a patient's bedside?

17 A. I am a hundred percent at the bedside.
18 It's because we have a hybrid model. So we actually
19 approve drug orders for patients on our floor or
20 other Intensive Care Units during the course of your
21 entire day. So you actually perform operational and
22 clinical duties at the same time Monday through
23 Sunday.

24 Q. Do you personally compound drugs in your
25 role as a clinical pharmacist at the University of

1 Chicago?

2 A. On occasion, yes, we have to.

3 Q. And who normally does the compounding of
4 preparations? I'm not asking for a name, I'm asking
5 for their role at the hospital.

6 MR. SUTHERLAND: Object to the form.

7 THE WITNESS: It would be a pharmacy
8 technician, unless the pharmacy technician is
9 not there or there's not one stationed in
10 your satellite, then it'd be the pharmacist,
11 or it's an emergency, which happens often.

12 BY MS. NELSON-MAJOR:

13 Q. And you don't personally administer the
14 drugs at the patient bedside, correct?

15 A. I have and do not, except in one
16 circumstance.

17 Q. And was that an emergency circumstance?

18 A. Correct, cardiac arrest, or RSI.

19 Q. Excuse me? Can you explain? You said
20 there was one circumstance, cardiac arrest or RSI.
21 Have you personally administered drugs during an
22 RSI?

23 A. That's correct, it would be in an
24 emergency. So if the provider -- if there's only
25 one anesthesia resident, you're helping them

1 actually to draw up the drugs and the doses, so that
2 can be pushed quickly into the IV line so they can
3 perform the intubation safely. Those would be the
4 emergency -- emergent situations only. Outside of
5 that, no.

6 Q. And to clarify, have you in fact
7 administered drugs during an RSI?

8 A. Over the last 20 years, yes. I can't
9 remember the number of times, but it's happened.
10 Cardiac arrest probably more frequently.

11 Q. And you also serve as the clinical
12 pharmacist for the perioperative area; is that
13 right?

14 A. Yes, ma'am.

15 Q. And what does perioperative mean?

16 A. It's a fancy word for the operating room
17 and procedural area.

18 Q. And in this capacity do you personally
19 determine the level of sedation or anesthesia
20 required for a particular procedure?

21 MR. SUTHERLAND: Object to the form.

22 THE WITNESS: Do we deter-- do I
23 determine the depth anesthesia. No, ma'am,
24 that's determined by the anesthesiologist or
25 the resident or the CRNA.

1 BY MS. NELSON-MAJOR:

2 Q. And once the anesthesiologist or CRNA
3 makes that determination, are you the person who
4 decides which drugs are the best choice for
5 achieving that particular level of sedation or
6 anesthesia?

7 MR. SUTHERLAND: Same objection.

8 THE WITNESS: No, ma'am, unless they
9 have a drug they don't -- they can't get or
10 they're out of or it's on shortage, which
11 unfortunately occurs these days.

12 BY MS. NELSON-MAJOR:

13 Q. And so outside of those circumstances, who
14 decides which drug will be appropriate to achieve a
15 desired level of sedation or anesthesia?

16 A. In the clinical hospital setting, it would
17 be the anesthesiologist or their resident or the
18 CRNA.

19 Q. And once that decision about which drug to
20 use has been made, are you in the operating room
21 when it's administered?

22 A. That's correct, I have been in the
23 operating room and been able to see medications
24 administered by every discipline.

25 Q. And as part of your routine day-to-day

1 duties, are you normally in the operating room when
2 those drugs are administered?

3 A. That's correct, that's our purpose of
4 being there.

5 Q. I'm looking at page two of your report.

6 A. Okay.

7 Q. And I'm looking at the first full
8 paragraph, which starts, "In addition to my
9 intensive care duties." Do you see that paragraph?

10 A. I have, yes.

11 Q. And I'm looking at the last sentence in
12 that paragraph, where you state that your role as a
13 clinical pharmacist in the perioperative area
14 requires a familiarity with drugs quote, "[used] in
15 Anesthesia Pain Management, generally and the
16 specific drugs in Tennessee's Lethal injection
17 procedures (midazolam, vecuronium bromide and
18 potassium chloride)."

19 What does anesthesia pain management mean?

20 A. Anesthesia pain management is just a
21 subsection of anesthesia.

22 Q. Is vecuronium bromide a drug used in
23 anesthesia pain management?

24 A. Within the operating room prior to
25 surgical incision, that's correct.

1 Q. And what about midazolam, is it used as an
2 anesthesia pain management?

3 A. That's correct, it would be the
4 pre-sedative generally given as a dose of one to two
5 milligrams, unless it's used for induction, it would
6 be higher.

7 Q. And what about potassium chloride, is it a
8 drug used in anesthesia pain management?

9 A. If they are covering a cardiovascular
10 room, that is correct, it would be given outside of
11 what the perfusionist is giving in response to a low
12 potassium level.

13 Q. And does anyone report to you in your role
14 as a clinical pharmacist?

15 A. No, ma'am.

16 Q. And do you report to anyone?

17 A. I report to the executive director, that's
18 correct.

19 Q. What percentage of the drugs dispensed
20 under your supervision as a clinical pharmacist are
21 compounded?

22 A. It would depend on the setting, scenario,
23 and circumstance.

24 Q. I'm asking about your job at the
25 University of Chicago Medicine, the circumstance

1 being your role as a clinical pharmacist. I'm
2 asking about whether in that setting and under that
3 scenario, what percentage of drugs are compounded
4 versus commercially manufactured.

5 A. Sure. Within the Intensive Care Unit it's
6 probably majority clini-- manufacturer, commercially
7 manufactured medications and drugs. Within the
8 perioperative space up to 25 percent to 50 percent
9 could be compounded preparations.

10 Q. And of the compounded drugs in that
11 perioperative area, what percentage would you say
12 are high-risk sterile preparations?

13 A. About 50 percent, half of them. It
14 depends on which supplier you're getting it from.
15 Majority are 503B, which are taking it from
16 non-sterile to sterile preparations, which is what
17 we use.

18 Q. You also list clinical coordinator
19 anesthesia and surgery on your resumé. What are
20 your duties in that capacity?

21 A. It's again working with the healthcare
22 providers, directly with the anesthesiologists, the
23 surgeons, and the Intensive Care Unit physicians,
24 and putting together a therapeutic plan.
25 Especially, when you have drug shortages; for

1 example, right now it's midazolam and potassium
2 chloride.

3 Q. And outside of your role as a clinical
4 pharmacist and a clinical coordinator, do you have
5 any other duties at the University of Chicago?

6 A. Outside of taking care of 30 surgical,
7 trauma and burn ICU patients in the perioperative
8 area, which is encompassed of about 100 cases a day,
9 no.

10 Q. Prior to your current job at the
11 University of Chicago, where were you employed?

12 A. I was at Rush University Medical Center.

13 Q. And what titles did you hold while
14 employed at Rush Medical Center?

15 A. I was the supervisor over the critical
16 care and the perioperative area. And I also worked
17 within different colleges for teaching, and that was
18 inclusive of the medical college, the graduate
19 college, which actually teaches Ph.D. students,
20 CRNAs, which are certified registered nurse
21 anesthetists, taught in that -- teach in that
22 program. And I was the course director for the
23 perfusionists, which actually administer
24 cardioplegia.

25 Q. And what topics did you teach in those

1 capacities?

2 A. Everything related to medications,
3 anesthetics, cardioplegia, and drug metabolism. So
4 it would be inclusive of pharmacokinetics, how the
5 drugs are broken down after they're given to the
6 patient; and pharmacodynamics, the clinical effect
7 after these medicines have been given in their
8 context in the setting.

9 Q. How long were you employed at Rush?

10 A. Gosh, it was the first job when I
11 graduated. So probably 18 years.

12 Q. And what motivated you to leave Rush?

13 A. There was a research opportunity and
14 platform at the University of Chicago, and their
15 grant endowment is significantly larger.

16 Q. Were your clinical duties at Rush
17 different than your clinical duties at the
18 University of Chicago?

19 A. No, the clinical duties are the same.

20 Q. How much of your time at Rush was devoted
21 to teaching versus clinical duties?

22 A. Teaching probably could be 10 percent,
23 15 percent, depends on the part of the year and the
24 course.

25 Q. And outside of your job at University of

1 Chicago and Rush, you've also served as an expert
2 witness; is that right?

3 A. Yes, ma'am.

4 Q. How long have you been doing expert
5 witness work?

6 A. That'd be north of 15 years.

7 Q. Approximately how many times have you been
8 deposed?

9 A. I don't recall. It'd probably be north of
10 a hundred.

11 Q. And can you approximate how many times
12 you've testified at trial as an expert witness?

13 A. Probably north of 50.

14 Q. Prior to this case, have you been involved
15 in any case in which a Department of Corrections was
16 involved?

17 A. No, ma'am, I don't believe so, not that I
18 recall.

19 Q. And is this the first lethal injection
20 case in which you've been involved?

21 A. As far as I can remember and I'm aware,
22 yes, that's correct.

23 Q. Who contacted you about getting involved
24 in this case?

25 A. I would believe it was Mr. Mitchell.

1 Q. And do you remember when that conversation
2 occurred?

3 A. No, I don't. It was at least a year ago,
4 maybe more.

5 Q. What is your view on the death penalty?

6 A. Well, I'm a U.S. citizen, and if it's
7 verified and allowed via the Constitution, and I
8 support the Constitution, I'd support it.

9 Q. What percentage of your time is devoted to
10 expert work versus your other duties at University
11 of Chicago or Rush?

12 A. About 10 to 20 percent. Just depends on
13 the year.

14 Q. Do you recall being retained by a man
15 named Kenneth Hail, who alleged that Aleve,
16 manufactured by Bayer, caused him permanent kidney
17 issues?

18 A. I do not, no, ma'am.

19 Q. So you don't recall being deposed in that
20 case?

21 A. I don't. I don't recall the case. I
22 apologize.

23 Q. Are you aware of any cases in which the
24 judge has disqualified you from offering an opinion
25 in a case?

1 A. If they have, I'm not aware of it. So,
2 no, ma'am, I don't know.

3 Q. I'm trying to pull up your report. If we
4 could go to the last page.

5 A. Okay.

6 Q. What is this list?

7 A. Oh, you mean the last page of the report.
8 One second.

9 Q. I'm sorry, the pdf, not the actual report.

10 A. Got it. Let me get there. I'm sorry. I
11 was asked to provide a list of cases in the last
12 four years.

13 Q. And how did you come up with this list?

14 A. I did the best from my memory and from
15 what I could scavenge through my e-mails.

16 Q. Do you recall being involved in a case
17 involving allegations that a flu vaccine caused the
18 death of a woman named Susan Halverson?

19 A. That does sound familiar, yes.

20 Q. Did you provide testimony in that case?

21 A. That does sound familiar, that's correct.
22 I think it was a number of years ago.

23 Q. Why was that case not included on your
24 list here?

25 A. Well, I thought it said last four years.

1 And if I remember right, I thought that one was
2 before that. I don't recall what year I testified.

3 Q. The Attorney Generals who retained you in
4 this case indicated that you participated in some
5 capacity in a case captioned: Shawn Taylor versus
6 Medical -- sorry, excuse me, Mercy Medical Center,
7 out of Maryland. Do you recall that case?

8 A. I don't, no, ma'am.

9 Q. I am pulling up a deposition transcript
10 that we'll e-mail to you, Mr. Sutherland.

11 MR. SUTHERLAND: Thank you.

12 Q. And while we're waiting for that to come
13 through, I wanted to ask a follow-up question. You
14 testified that we don't know what 240 mil
15 equivalents of potassium chloride would feel to an
16 awake person, correct?

17 A. 240 mil equivalents split up into 60 cc's,
18 so 120 actually at a time? No, I don't know what
19 that would feel like in that concentration.

20 Q. So did you consider potential effect of
21 potassium chloride would have on the inmate when
22 you opined that midazolam was an appropriate first
23 drug in the TDOC protocol?

24 A. I did, yes. Because my opinion is, is
25 that the inmate would be rendered insensate,

1 unconscious and unable to respond to physical
2 stimuli.

3 Q. And if you don't know what the potassium
4 chloride would feel like when administered, how do
5 you know what level of sedation would be appropriate
6 to render an inmate insensate to that unknown,
7 according to you, stimulus?

8 A. Based on 250 milligrams given
9 intravenously about a minute apart would render a
10 person unconscious and unable to respond to physical
11 stimuli.

12 Q. And it's your opinion that regardless of
13 the severity or magnitude of a stimulus presented by
14 the potassium chloride, that dose of midazolam would
15 be adequate.

16 A. 250 milligrams intravenously, set apart by
17 about a minute, given in total of 500 milligrams,
18 yes, ma'am, that would be adequate.

19 MR. SUTHERLAND: I just sent the
20 transcript.

21 A. Okay.

22 Q. I'm going to mark this transcript as
23 Exhibit 17.

24 Do you recall being deposed in this case
25 captioned: Estate of Elena Chavez versus Dignity

1 Health?

2 A. I don't, no.

3 Q. And why was it not included on your list
4 of cases in which you've offered testimony in the
5 last four years?

6 A. I think I just told you, it's because I
7 don't recall the case. I don't have any record.

8 Q. And you earlier said that you reviewed
9 your e-mail when compiling this list; is that right?

10 A. That's correct.

11 Q. And can you explain to me how you went
12 about reviewing your e-mail to compile the list of
13 cases in which you've testified?

14 A. Yeah, I basically looked at the inbox or
15 anything sent, because the trash is completely
16 empty. So I tried to find whatever I could the best
17 way I could to supply a list. And so I put forth a
18 good faith effort to do so.

19 MS. NELSON-MAJOR: Mr. Sutherland,
20 Dr. Patel, can we take a five-to-ten-minute
21 break? I'm nearly finished, but I just want
22 to --

23 MR. SUTHERLAND: Yeah, sure. Like --
24 whatever you like.

25 MS. NELSON-MAJOR: 3:30/4:30?

1 MR. SUTHERLAND: Yep, that's fine.

2 VIDEOGRAPHER: Going off the record,
3 the time is 3:18.

4 (A brief recess was taken.)

5 VIDEOGRAPHER: Back on the record, the
6 time is 3:33.

7 BY MS. NELSON-MAJOR:

8 Q. Dr. Patel, I want to ask you a couple more
9 questions about your previous expert testimony work.

10 Do you keep copies of the expert reports
11 that you write in these cases?

12 A. No, ma'am, due to, I believe most of them
13 now, for the last 10, 15 years come with -- at least
14 10 years for sure -- HIPAA agreements that you
15 destroy all materials related to the case. So
16 whether it does or not, it's an active practice, I
17 just -- they go to the shredder. Some companies/
18 firms want them sent back, so you send it back.

19 Q. And when you write an expert report in a
20 case, how do you provide it to the attorneys that
21 have retained you?

22 A. Usually it's e-mailed, unless it's
23 discussed over the phone.

24 Q. So in some cases you provide your expert
25 report over the phone?

1 A. It would be discussing my thought
2 processes and opinions on the phone, that's correct.

3 Q. And do you go through and delete the
4 e-mails that you've sent to attorneys providing them
5 with expert reports?

6 A. I do. I don't have a reason to keep them,
7 so I get rid of it. It just clutters the e-mail.

8 Q. And how soon after you provide a report to
9 an attorney in a case do you delete that e-mail?

10 A. Probably after I sent it. I don't have
11 any use for it.

12 Q. And so as soon as you send an e-mail to an
13 attorney in a case, you then go ahead and delete the
14 e-mail, the sent e-mail?

15 A. After I'm done sending any e-mail, if I've
16 deleted it, the trash is emptied. So, yeah, I don't
17 have any reason to keep any of that stuff, it's
18 gone.

19 Q. No, my question is, how soon after sending
20 the e-mail with your report do you then go and
21 delete that sent e-mail from your e-mail account?

22 A. Oh, I see what you -- I don't do anything.
23 Gmail does it all, it's already gone.

24 Q. So you're saying that Gmail automatically
25 deletes your sent mail?

1 A. You can set it up that way, that's
2 correct, so it doesn't clutter your box.

3 Q. And so you have your Gmail set up to
4 automatically delete an e-mail as soon as you send
5 it?

6 A. Sent and anything put in trash.

7 Q. So are you saying that Gmail deletes the
8 e-mail for you automatically or you delete the sent
9 e-mail?

10 A. I don't delete anything. It was set up so
11 I -- because I had too much clutter in the e-mail
12 inbox.

13 Q. I'm talking about your sent mail folder,
14 not your inbox. You have Gmail set up to
15 automatically delete every e-mail that you send?

16 A. The inbox one, I believe, is like on a
17 rotation. The sent, I believe, if I remember right,
18 was something like 30 or 60 days. The trash is
19 automatically emptied once it goes in there.

20 Q. And when you searched your e-mails for the
21 cases in which you previously testified over the
22 past four years, did you type in a search word or
23 did you manually scroll through your inbox?

24 A. No, I just tried to look for either sent
25 invoices or things like that.

1 Q. Do you keep copies of your billing records
2 in these cases?

3 A. No. No, ma'am, unless -- not unless
4 they're active.

5 Q. So you delete your billing records as soon
6 as you're done with a case?

7 A. Yeah, I don't have any need for them.
8 They send -- I forget the name of the form, but they
9 send it every January or February and then that just
10 goes to the accountant.

11 Q. Who's "they"?

12 A. The firm sends whatever, I forgot the
13 form, W-9 or something like that, for taxes.

14 Q. And so when the firm sends you a W-9, you
15 forward it to your accountant?

16 A. Well, I don't -- they don't -- they send
17 it via paper mail or snail mail, and then I have to
18 huck all of those over to the accountant, they take
19 care of it, and then the accountant has it on file,
20 I'm sure.

21 Q. And do you not keep any records of your
22 billing besides the one that you've send to the
23 accountant?

24 A. No, I don't, ma'am.

25 Q. Do you report the income that you earn

1 through your expert work to the IRS?

2 A. Yes, ma'am, as required.

3 Q. Do you keep copies of your tax records?

4 A. I keep copies of my tax records, yes,
5 ma'am.

6 Q. And for the documents that you receive
7 from attorneys on these cases, what do you do with
8 those documents?

9 A. Are these active cases or completed?

10 Q. Let's start with active cases. What do
11 you do with documents when you receive them from an
12 attorney while the case is active?

13 A. Well, majority now is ShareFile. So
14 they're just different links that are sitting in the
15 e-mail system.

16 Q. And then when the case is no longer
17 active, what do you do with the documents?

18 A. I don't do anything, except delete the
19 e-mail for the link for the ShareFile, whether
20 it's -- it's generally like a firm secure link, it
21 could be Dropbox, those kinds of things.

22 Q. And how do you know when a case is no
23 longer active?

24 A. They will let you know.

25 Q. And who's "they"?

1 A. The firm that hired me.

2 Q. So once you're told that a case is no
3 longer active, you go through and you delete the
4 particular e-mail with the ShareFile link; is that
5 correct?

6 A. That's correct. And if they sent anything
7 over in paper, it goes to the -- next time I take it
8 to the shredder.

9 Q. And you delete the copy of the reports
10 that you send via e-mail?

11 A. That's correct. I don't have any use for
12 those.

13 Q. And you delete the drafts of the report
14 that you might have saved on your computer?

15 A. That's correct.

16 Q. And you delete all the invoices that
17 you've sent to the attorneys?

18 A. At that time point, that's correct, after
19 everything's been submitted and paid.

20 Q. And to do that, do you go back through
21 your e-mail to find every e-mail related to a
22 particular case and delete it?

23 A. That's correct.

24 Q. And do you do that because you have a
25 document retention policy that says that you should

1 be doing that?

2 A. Correct. To expand, it's inclusive of
3 HIPAA. And in my world, where we actually work with
4 humans and patients, HIPAA is anything with the
5 patient name or an identifier. The invoice has that
6 information, so I delete it and I honor what they
7 ask.

8 Q. And so you're saying that HIPAA governs
9 your expert witness work in these cases.

10 A. No, I'm saying I'm concerned about patient
11 information and identifiers. And in my world,
12 anything that connects a case to a patient, I would
13 think is an identifier. So I remove it because I
14 have no need for it, and I don't want anything
15 attached in violation of that. And so I respect
16 whatever they ask me to do.

17 Q. And "they" being the firm?

18 A. That's correct. It could be a plaintiff
19 firm or a defense firm.

20 Q. And so those firms have instructed you to
21 delete all of this information once the case is
22 closed?

23 A. That's correct. It's a general statement
24 of "Delete all records." And, to me, all records is
25 anything related to the case in the file.

1 Q. Do you have a secretary?

2 A. No, ma'am, I don't have a secretary.

3 Q. And when you're working on a case, how do
4 you keep track of the time that you're billing?

5 A. A Post-it, usually.

6 Q. So you have a series of Post-its on your
7 desk for each case that you're currently working on?

8 A. No, right now I don't have any. It's a
9 Post-it on a case of anything that I'm actively
10 reviewing, and once I've compiled the hours, similar
11 to today, I would just send the invoice and throw
12 the Post-it out, gets shredded.

13 Q. Are you keeping track of the hours that
14 you worked on this case on a Post-it note?

15 A. That's correct. Not a Post-it note. I
16 actually have a Word document, because it's been --
17 since my last invoice it's probably been at least
18 two months, maybe a month and a half.

19 Q. Do you delete your Word documents with the
20 hours that you work on a case after it's closed as
21 well?

22 A. That's correct. I don't have any reason
23 for any of those. Once it's been paid.

24 Q. How many invoices have you submitted in
25 this case?

1 A. I think one, which was, I thought, back in
2 December. And I haven't prepared the second. I've
3 started to.

4 Q. Have you already deleted the invoice that
5 you created in this case?

6 A. I believe so. But I believe the -- the
7 office has it. I'm sure they can provide it, if you
8 want.

9 Q. So if you delete your invoices as you go,
10 how do you know that the firm or the attorney that's
11 retained you is paying the appropriate amount?

12 A. I only get rid of it after it's been paid,
13 and it's been paid, so I don't have any need for it.

14 Q. Have you been required to prepare the type
15 of list that we just were talking about, on the
16 cases in which you've testified previously, in other
17 cases?

18 A. Over the last 15 years, I'm sure I've been
19 asked to, yes.

20 Q. And do you also delete those lists after
21 you prepare them?

22 A. After they're sent, that's correct. I
23 don't have any need for it.

24 Q. Dr. Patel, in your opinion, will
25 500 milligrams of midazolam be sufficient to render

1 a patient insensate to the painful -- to painful
2 surgical stimulus?

3 MR. SUTHERLAND: Object to the form.

4 THE WITNESS: My opinion is, is that it
5 will render a person unconscious and unable to
6 respond to physical stimuli.

7 BY MS. NELSON-MAJOR:

8 Q. My question was more specifically, would
9 it be sufficient to render someone insensate to
10 painful surgical stimuli?

11 MR. SUTHERLAND: Objection to the form.

12 THE WITNESS: Surgical stimuli? You'd
13 have to ask a surgeon.

14 BY MS. NELSON-MAJOR:

15 Q. So you're rendering an opinion that
16 500 milligrams will be sufficient for a physical
17 stimulus in general, but you're not able to render
18 an opinion on the particular question of whether it
19 would render a someone insensate to a painful
20 surgical stimulus?

21 A. That's correct, because surgical, depends
22 on the procedure, and I'm not a surgeon.

23 MS. NELSON-MAJOR: Can we take a
24 two-minute break? I think we're about done.
25 But if we could take a two-minute break and go

1 off the record, then we should be able to
2 finish.

3 MR. SUTHERLAND: Sure.

4 VIDEOGRAPHER: Off the record, the time
5 is 3:44.

6 (A brief recess was taken.)

7 VIDEOGRAPHER: Back on the record, the
8 time is 3:46.

9 MS. NELSON-MAJOR: I have no further
10 questions for Dr. Patel. But I do want to
11 thank Dr. Patel for his time today, so thank
12 you.

13 MR. SUTHERLAND: Thank you, Ms. Nelson-
14 Major, and thank you everybody else. Hope you
15 have a good weekend.

16 THE WITNESS: Appreciate it. Thank
17 you.

18 MS. NELSON-MAJOR: Thank you, Mr. Ely
19 and Ms. Davis.

20 VIDEOGRAPHER: This is the conclusion
21 of the deposition, the time is 3:47, going off
22 the record.

23 (Off the record and deposition
24 concluded.)
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C E R T I F I C A T E

STATE OF TENNESSEE)
)
COUNTY OF KNOX)

I, Brenda L. Davis, LCR, RPR, RMR in and for the State of Tennessee, do hereby certify that the above deposition was reported by me and that the foregoing # pages of the transcript are a true and accurate record to the best of my knowledge, skill, and ability.

I further certify that I am not related to nor an employee of counsel or any of the parties to the action, nor am I in any way financially interested in the outcome of this case.

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[administered - anesthesiologist]

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[asking - batch]

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Tennessee Rules of Civil Procedure
Depositions Upon Oral Examination
Rule 30

Rule 30.05: Submission to Witness; Changes;
Signing.

When the testimony is fully transcribed the deposition shall be submitted to the witness for examination and shall be read to or by the witness, unless such examination and reading are waived by the witness and by the parties. Any changes in form or substance which the witness desires to make shall be entered upon the deposition by the officer with a statement of the reasons given by the witness for making them. The deposition shall then be signed by the witness, unless the parties by stipulation waive the signing or the witness is ill or cannot be found or refuses to sign. If the deposition is not signed by the witness within 30 days of its submission, the officer shall sign it and state on the record the fact of the waiver or of the illness or absence of the witness or the fact of the refusal to sign together with the reason, if any, given therefor; and the deposition

may then be used as fully as though signed unless on a motion to suppress under Rule 32.04(4) the court holds that the reasons given for the refusal to sign require rejection of the deposition in whole or in part.

DISCLAIMER: THE FOREGOING CIVIL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY. THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE STATE RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

VERITEXT LEGAL SOLUTIONS
COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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